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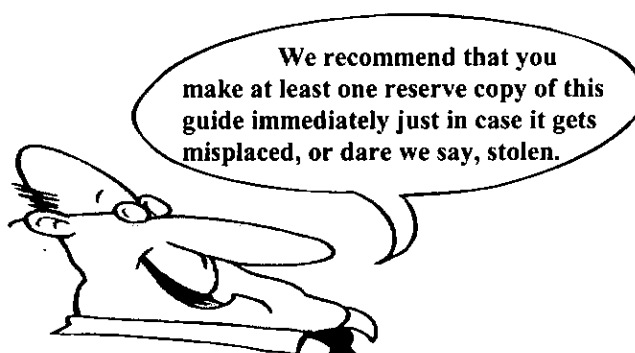# TABLE OF CONTENTS (Cont'd.)

INTRODUCTION

INTRODUCTION

This guide was developed for use by state agency and drug labeler personnel responsible for activities relating to the Medicaid Drug Rebate Program, e.g., calculating and reporting drug pricing data, preparing invoices, reporting utilization data, receiving and reconciling invoices, quarterly drug rebate payments, and dispute resolution. The guide provides a quick, easy reference source to assist in the daily operation of the drug rebate program by simplifying complex processes and converting statutory language into plain words. For the purpose of this guide, the term "labeler" is used to refer to manufacturers, repackagers, and relabelers.

Guide Format

- **Individual Sections** - Topical sections are provided for quick and easy reference. In addition to sections relating to statutory and program operational requirements, sections are provided for such items as program definitions, index, acronyms, and a CMS Drug Rebate Directory.

- **Binder construction** - The use of binders provides the best method to insert or delete guide material when necessary, easily copy the guide, or distribute guide sections among those responsible for various activities in the program. CMS will distribute additions and/or replacement pages to the guide, as needed.

- **Cross referencing** - Many sections of the guide purposely contain information found in other sections. Although it may seem repetitive, it is done to provide the least frustration when researching a particular subject matter that overlaps another or requires the use of forms.

We recommend that you make at least one reserve copy of this guide immediately just in case it gets misplaced, or dare we say, stolen.

✎NOTE: This Medicaid Drug Rebate Operational Training Guide is intended for the use of labeler and state staff involved in the daily operational process of the drug rebate program. The guide is intended as guidance; it is not intended as a revision or modification of the requirements set forth in section 1927 of the Act, the rebate agreement, program releases, or any regulations. In the event that any part of this guide conflicts with any of the foregoing, the Act, rebate agreement, program releases, and regulations take precedence.

CLARIFIER: For purposes of this guide, the words/acronym "product(s)," "drug," "drug products," and "NDC" all have the same meaning as covered outpatient drug as defined in section 1927 of the Act and the rebate agreement.
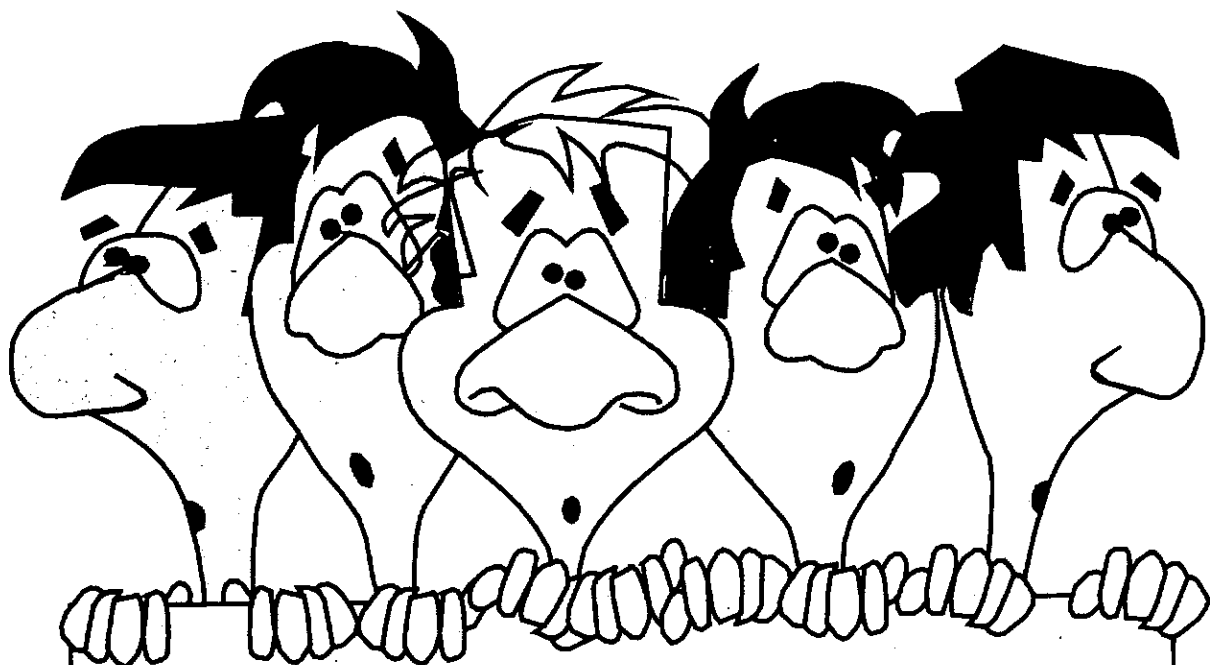
PROGRAM

ORIENTATION

PROGRAM ORIENTATION

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration) is responsible for overseeing the Federal Medicaid program (title XIX of the Act).

For the purpose of this guide, there are four pieces of legislation which affect title XIX of the Act:

> The Omnibus Budget Reconciliation Act of 1990
> The Veterans Health Care Act of 1992
> The Omnibus Budget Reconciliation Act of 1993
> The Balanced Budget Act of 1999

THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990, section 4401, amended title XIX of the Act by adding section 1927 which requires rebate agreements for covered outpatient drugs, better known as the Medicaid Drug Rebate Program.

Section 1927 of the Act, **effective January 1, 1991**, sets forth the requirements of the Medicaid Drug Rebate Program. In general, in order for Federal Medicaid matching funds to be available to States for covered outpatient drugs of a labeler, the labeler must enter into and have in effect a rebate agreement with the Federal government. Without an agreement in place, States can not generally receive Federal funding for outpatient drugs dispensed to Medicaid beneficiaries. Rebate amounts received by States are considered a reduction in the amount expended by States for medical assistance for purposes of Federal matching funds under the Medicaid program.

A rebate agreement requires the labeler to pay each State a quarterly rebate for their covered outpatient drugs paid by the State during the quarter. The agreement also requires the labeler to provide pricing information to CMS. This information consists of the average manufacturer price (AMP) and the labeler's best price (BP) for covered outpatient drugs for each quarter. In turn, the labeler receives information from the States on the total number of dosage units of each covered outpatient drug paid for during the quarter. The labeler remits to the State a rebate payment based on the number of units paid for and the unit rebate amount (URA). The URA is calculated using the formula set forth in section 1927 of the Act and detailed in section H of this guide.

THE VETERANS HEALTH CARE ACT OF 1992 (VHCA) was enacted on November 4, 1992, and amended section 1927(a) of the Act. The effects of the VHCA of 1992 relate to coverage of labelers' drugs, duplicate payments, rebate calculations, and BP. Specifically, the VHCA:

1. Requires all labelers to enter into a drug pricing agreement with the Public Health Service (PHS), and that labelers of single source and innovator multiple source drugs, biologicals, or insulin enter into a master agreement with the Department of Veterans Affairs, in order to continue receiving Medicaid coverage of their products.

2. Prevents a labeler from paying a Medicaid rebate on discounted drugs sold to PHS covered entities.

3. Increases the rebate calculation for single source and innovator multiple source drugs to 15.7% of AMP through December 1993, and removes the 50% CAP of AMP beginning 1/1/93.

4. Requires labelers to exclude from BP any prices charged to specific entities (see pricing data definitions in section F of this guide for a list of the entities involved).

The detailed effects of the VHCA are discussed throughout this guide in their respective section(s).

THE OMNIBUS BUDGET RECONCILIATION ACT OF 1993 was enacted by the Congress on August 10, 1993, and became effective on October 1, 1993. This legislation effected major changes to the Medicaid Drug Rebate Program regarding single-source and innovator multiple-source drugs approved by the Food and Drug Administration after October 1, 1990. Specifically, the legislative change affects the Baseline AMP and the Baseline Consumer Price Index-Urban (CPI-U), which ultimately impacts the computation of the URA. (Baseline AMP, Baseline CPI-U, and the URA computation are discussed in sections F and H of this guide.)

THE BALANCED BUDGET ACT (BBA) OF 1999 changed the date a new labeler's products can be covered under the Drug Rebate Program from the first day of the quarter that begins more than 60 days after the postmark of the signed rebate agreement to the actual date of the postmark of the signed rebate agreement. This "immediate" coverage of the new labeler's drugs is optional to each state, whereby a state may elect to begin coverage from the postmark date to the mandatory date (quarter starting more than 60 days after the postmark). Beginning on the mandatory date, all states must cover this labeler's products.

..IN THE BEGINNING...

When the Drug Rebate Program began in 1991, a list of several thousand drug companies, along with names and addresses, was acquired by CMS from the FDA. CMS conducted a mass mailing in an attempt to contact all, or at least the vast majority, of drug manufacturers, repackagers, relabelers, and any other entities that may need to enter into this new program in order to continue to have their products covered in the State Medicaid Programs. There were over 1,000 packages sent out with a letter explaining what the program was about and why they should sign and return the contract. Also, included was a CMS "Hotline" phone number by which we would answer questions about the program and what it meant to sign the agreement. Due to the limited volume of calls received after the fourth year of the program, the "Hotline" was discontinued in 1995 at the time of CMS's physical move to a single site location. In its place, CMS distributed to all labelers and states a list of Drug Rebate Team members, their phone numbers, and their primary responsibilities.

Originally, there were about 250 responses from CMS's mailing, mostly from the larger companies, a few of which were already somewhat familiar with the program. By the time the program really got rolling, we were into the second half of 1991 and had successfully included about 340 companies in the original group.

..TODAY...

There are in excess of 500 labelers participating in the Medicaid Drug Rebate Program. New drug companies and currently established companies that now wish to be included in the Drug Rebate Program will generally get in touch with CMS's Drug Rebate Team through contacts at state agencies. The first thing new companies must do after receiving the Drug Rebate Agreement package from CMS is to read the agreement, complete the signature page of the agreement (see section C of this guide), fill out all contact information attached to the agreement, and send both items to the address provided in CMS's cover letter. After CMS

receives the completed contract and attachments, the drug company is established on CMS's drug rebate data base and a letter of acceptance is sent to the company along with both the optional and mandatory starting dates of their participation in the program.

The labeler's start date depends on the date CMS receives the signed rebate agreement. Generally, a labeler's start date is the first day of the first quarter that falls more than 60 days from the postmark of their signed agreement. For example, an agreement postmarked on April 30 will result in a start date of July 1. A postmark, however, of May 8 may delay the start date until the quarter beginning October 1.

NOTE: PLEASE SEE THE WRITE-UP EARLIER IN THIS SECTION THAT EXPLAINS THE OPTIONAL LABELER'S STARTING DATE UNDER THE BBA OF 1999.

MEDICAID DRUG REBATE AGREEMENT

(Exclusive of enclosures B-F, data forms
and definitions. These enclosures are sent
with the rebate agreement package to
prospective participants in the program.
The content of these enclosures is discussed
in various areas throughout this guide.)

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) "Quarter" means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II   MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III   SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b)   The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV   PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V   DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI   DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII   CONFIDENTIALITY PROVISIONS

(a)   Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII   NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX   GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

> Center for Medicaid and State Operations
> Family and Children's Health Programs Group
> Division of Benefits, Coverage and Payment
> Post Office Box 26686
> Baltimore, MD 21207-0486

Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The CMS address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to CMS at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X   APPENDIX

Appendix A attached hereto is part of this agreement.

XI   SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:_____   _____

                                                  Date

Title: Deputy Director
        Finance, Systems and Quality Group
        Center for Medicaid and State Operations
        Centers for Medicare & Medicaid Services
        Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____   _____

                  (signature)   (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____

CONFIDENTIAL

D1

<u>CONFIDENTIALITY</u>

Section 1927(b)(3)(D) of the Act and the Medicaid Drug Rebate Agreement state that information disclosed by labelers is confidential and shall not be disclosed in a form which discloses the identity of a specific labeler, or prices charged by labelers. This provision covers all states as well as CMS.

Although the statute provides for three exceptions to the disclosure of labeler/prices, data related to prices are generally subject to both privacy and trade secret restrictions and are not released by CMS and must not be released by states. The pricing data CMS receives is held in the strictest confidence and maintained only on CMS's master files. CMS sends URAs to states, but actual pricing data goes no farther than CMS.

The three exceptions to data disclosure are data that are: 1) public knowledge; 2) legally obtainable from other sources; or, 3) not considered confidential. CMS complies with these requests for data.

In accordance with the Drug Rebate Agreement, labelers will hold state Medicaid utilization information confidential. This includes additional information on original data received and any information acquired during audits of such data. Except where otherwise specified in the Act or the agreement, the labeler will observe state confidentiality statutes, regulations, and other properly promulgated policy.
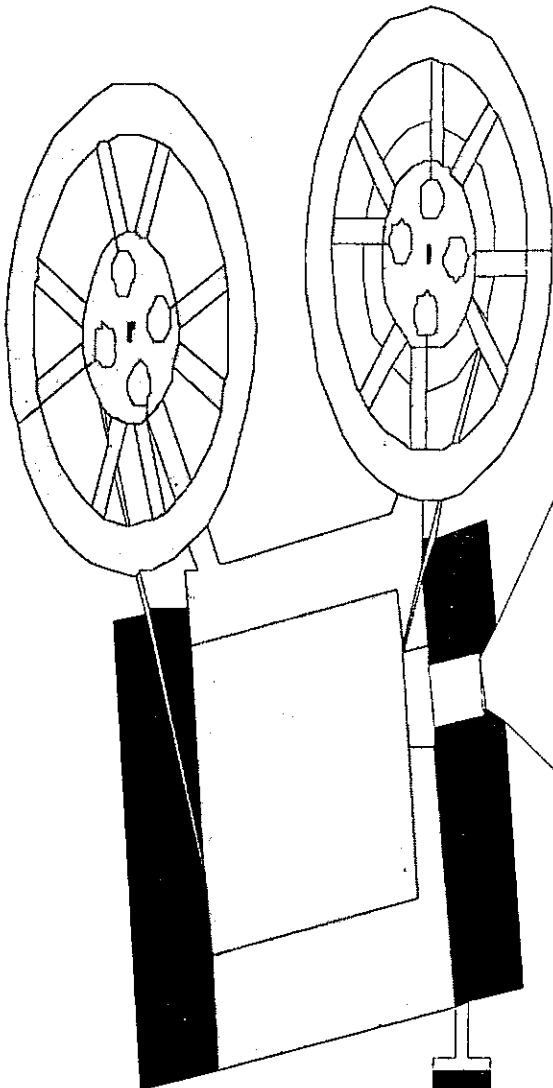
PROGRAM

OVERVIEW

PROGRAM SYSTEM
AND
GENERAL REPORTING

This section describes the drug rebate program data system and gives a general outline of the data flow of a quarterly rebate cycle, from labelers to CMS, CMS to states, states to labelers/CMS, and finally, labeler rebate payments to states.

CMS's data system for the drug rebate program is called the Medicaid Drug Rebate Initiative (MDRI) master file. The general setup of the MDRI system begins with Baseline data generated by the labelers. Baseline data consists of the "profile" of each product that has a National Drug Code (NDC) sent to CMS using a specific record layout and containing specific data. DESI Indicator, Therapeutic Equivalency, Unit Type, and Drug Category are just a few examples of the data required to establish an NDC on the MDRI system. (See section F for the detailed record layout and data elements required.)

Baseline data for all covered outpatient drugs are <u>submitted initially within 30 days</u> after the end of the quarter of the new labeler's optional start date. (CMS provides new labelers with both the optional and mandatory starting date for their participation in the program.) From this point on, when submitting quarterly pricing data, a labeler **MUST** also include Baseline data for every <u>new</u> NDC that has a Market Date in the reporting quarter. For example, if a product is entering the market on 11-05-01, the Baseline data **MUST** be included in the 01-4 quarterly pricing data submission, due to CMS before the end of January, 2002.

Once a labeler is participating in the program, current quarter pricing data, along with prior quarter updates and additions are due to CMS within 30 days after the end of each calendar quarter.

CMS processes the quarterly data and sends edit reports to labelers for data rejected by the system. If labelers can correct information shown on the edit report and return the data to CMS before the system is shut down for rebate calculations, the corrected data will be entered and included in that quarter's unit rebate calculations. (Edit reports are discussed in detail in section G.)

The MDRI system shutdown occurs within 45 days after the quarter ends. The URAs are generated and tape/data cartridges are created and mailed to all 50 states and the District of Columbia. The states should update their master drug rebate files to reflect information contained on the CMS tape, verify URA adjustment data with labelers' rebate payments, and incorporate all current quarter URAs into their file for billing purposes. In addition to URA data, the CMS tape contains an updated labeler contact name and address file. States should also overlay their labeler contact files each quarter to reflect this updated information.
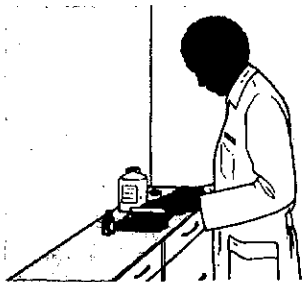
Within 15 days after receiving the URA data tape from CMS, states must submit invoices to each labeler for any NDCs the state reimbursed a pharmacy for during the past quarter. States also must submit utilization adjustment records (unit changes) for past quarters where units billed are determined to be incorrect.

State invoicing to labelers can be submitted using several media. It is the state's option whether to submit invoices in paper form, by diskette, or electronically. CMS does not mandate the reporting media for invoices, however, the collection of the invoice data and its reporting format (data fields/elements) are mandated. (See State Invoice, Section F.)

For all invoicing, each state must generate a separate record for each NDC billed to the labelers and submit a tape to CMS containing all utilization for the quarter. That is, whatever the state invoices to labelers each quarter, that same information MUST be submitted to CMS. CMS uses the utilization data received on the states' tapes for internal studies as well as reports to the Congress, the Inspector General, and Government Accounting Office.

Within 38 days after the postmark of the state invoice, labelers are required to pay rebates to states for all invoiced NDCs, except for those which are disputed by the labeler. All disputes must be initiated based on units and must be for "reasonable" cause. The dispute can involve the entire number of units per NDC, or any portion thereof. (The Dispute Resolution Program is discussed in section K of this guide.)

Payment to the states using the correct rebate amount is, ultimately, the responsibility of the labeler; thus, many calculate and pay states based on their unit rebate amounts rather than the rebate amount calculated by CMS. If an invoiced URA is different from the one calculated by the labeler, it is up to the labeler to research the difference and determine if it calculated the URA incorrectly or if pricing data sent to CMS was not correct. If the labeler's URA calculation is inaccurate, the labeler is to correct its baseline/pricing data and pay the state(s) using the CMS URA. If the labeler URA is correct, the labeler must change the URA and total amount due on the invoice, include a ROSI form, send the documentation to the state and send pricing or price-related data corrections to CMS. CMS will generate PPA records for the corrected NDC and include the PPAs on the next quarterly URA tape. These PPAs are used by the state to verify that the labeler's URA is correct.

Additionally, under the following specific condition, labelers are allowed to correct utilization on an invoice. If an invoice arrives and an apparent error in utilization of an NDC is reported, the labeler is instructed to contact the rebate contact at the state and discuss the findings. If, after examination, the state analyst agrees with the labeler's findings, the labeler can change the utilization, calculate total rebate due and include a ROSI with payment to the state.

In addition to product data reporting, labelers are required to report administrative data to CMS. This data consists of contact individuals involved in the program and a data transmission option form. The latter of these requirements (form 367c) is generally considered a one-time submittal, but can be updated as the need arises. Historically, the labeler contact data is ever-changing and labelers are required to submit these changes on the OMB approved form 367a. It is imperative that ALL changes (area code,

phone number, extension, name, etc.) are reported to CMS as soon as possible after the change occurs. If not, all the states and CMS will have incorrect contact data which could cause problems in the quarterly process.

States also are required to report administrative data to CMS consisting of contact individuals for technical, policy, and invoice matters. Form 368 was developed and approved by OMB for this purpose. As with the labelers, states are also encouraged to report ALL contact changes immediately to avoid problems and delays in the quarterly process.

MEDICAID DRUG REBATE PROGRAM

STATES

UTILIZATION DATA
(INDIVIDUAL INVOICES)

REBATE

LABELER

REBATE DATA
(PER UNIT)

UTILIZATION DATA

CMS

PRICING INFO

ANNUAL
SUMMARY REPORTS

CONGRESS
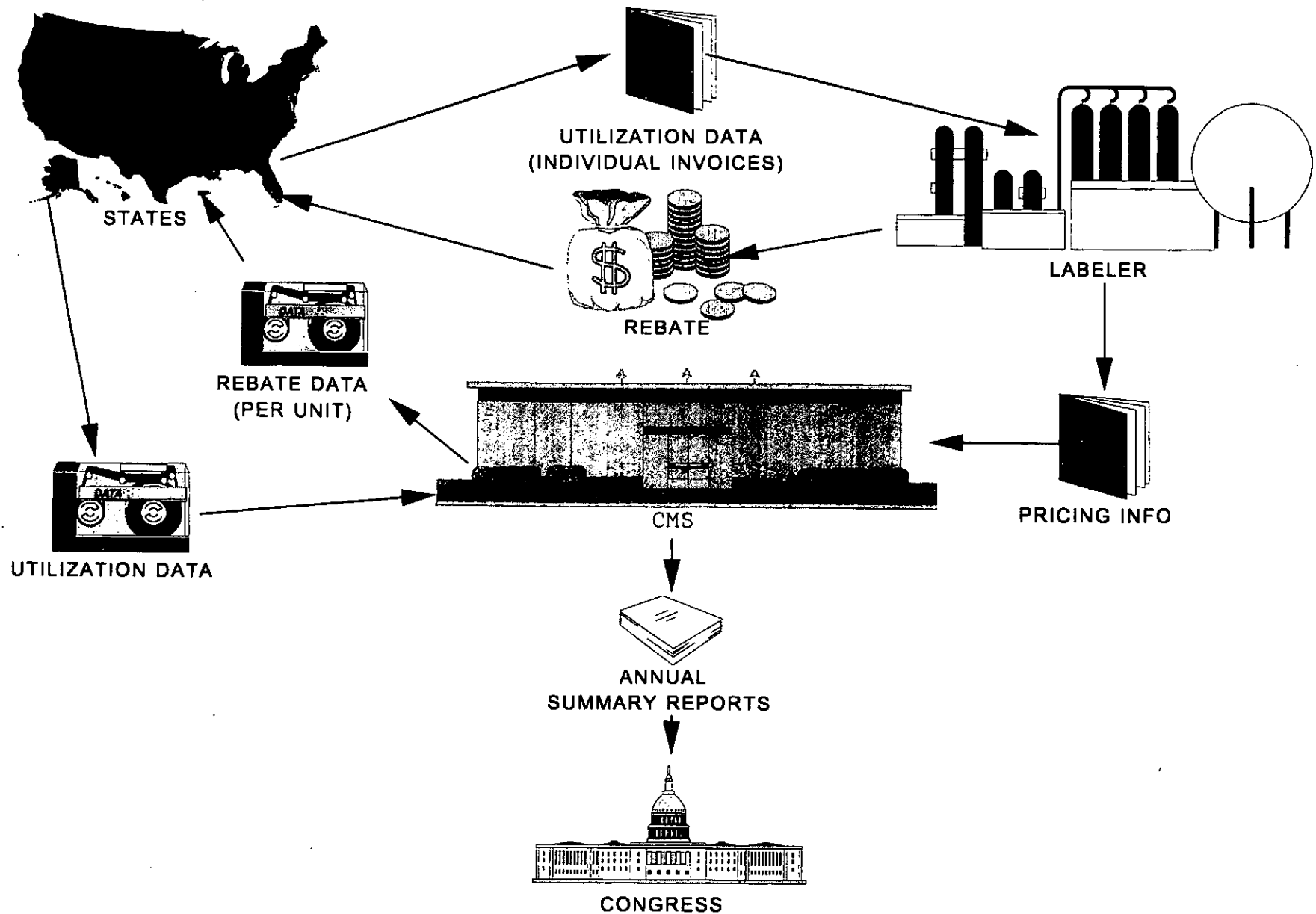
MEDICAID DRUG REBATE PROGRAM
QUARTERLY EVENT TIMELINE

```
                                                      ┌──────────────┐
                                                      │ W/I 38 DAYS  │
                                                      │ OF POSTMARK  │
                                                      └──────────────┘
     DAY 30              DAY 45          DAY 60                   DAY 90
```

DAYS 1 THRU 30 | DAYS 31 THRU 45 | DAYS 46 THRU 60

NEW LABELERS (Mandatory Coverage)	CMS VALIDATES DATA	STATES GENERATE AND SEND REBATE INVOICES TO LABELERS FOR PREVIOUS QUARTER'S REBATES	ALL STATES REPORT UTILIZATION DATA TO CMS
SIGN AND POSTMARK CONTRACT WITHIN FIRST 30 DAYS OF THIS QUARTER (60 DAYS PRIOR TO NEXT QUARTER) TO BE INCLUDED IN NEXT QUARTER	CMS VALIDATES NDCs USING FDA DATABASE CMS CALCULATES PER UNIT REBATE AMOUNTS CMS GENERATES DATA TAPES/CARTRIDGES FOR STATES		

EXISTING LABELERS *	NEW LABELERS (Optional Coverage)	EXISTING LABELERS ONLY
SUBMIT PRICING AND NEW PRODUCT BASELINE DATA TO CMS FOR PREVIOUS QUARTER	SIGN CONTRACT AT ANYTIME TO BE INCLUDED IN THE PROGRAM AT EACH STATE'S OPTION, USING THE POSTMARK AS THE STARTING DATE	SUBMIT REBATES TO STATES BASED ON ALL UNDISPUTED INVOICE ENTRIES

* EXISTING LABELERS INCLUDES ALL NEW LABELERS WITH AN AGREEMENT POSTMARK DATE ANYTIME IN THE LAST QUARTER

E6

PROGRAM

REQUIREMENTS

PREFACE

In this section, we will be discussing the data elements included on the CMS URA quarterly tape sent to all states. This preface is an explanation of why it is imperative that states use data fields from the CMS URA quarterly tape, rather than values from independent software companies that supply data to the states.

Quarter after quarter, CMS receives phone calls from drug labelers stating that:

> ➤ the URA(s) reported by states on the invoice does not match what should have been calculated from the AMP/BP values sent to CMS;

> ➤ the units reported on the invoice do not match a multiple of the labeler's UPPS supplied with their Baseline data; and

> ➤ the Unit Type does not match that which they supplied to CMS.

Information on the CMS URA tape, such as Unit Type and UPPS are created from values supplied by labelers. These values (e.g., 30 ML rather than 28.7 ML = 1 oz for a tube of ointment) are used by the labelers when calculating their AMP and BP values. Whatever values are used by a particular labeler, those values are reported to CMS and are contained on the quarterly URA tape.

Another value contained on the URA tape is the DESI value. This DESI value is used by CMS in determining whether Federal Financial Participation (FFP) will be paid IN THE FOLLOWING QUARTER for a given product. If a state uses a DESI code from an outside source, it could be paying for a drug for which FFP is not available.

By using values supplied by an outside concern, states run the risk of using values inconsistent with those of the labeler. The use of such values causes erroneous data in the state's system, delayed processing of invoices by the labelers, possible loss of FFP, and is often a major reason for disputes.

Even after more than 10 years of running the drug rebate program, there are some states that do not use the quarterly CMS URA tape to process their drug rebate data. In an attempt to prevent the use of erroneous data due to this practice, quarter after quarter, we include all data from the quarterly URA tape (MINUS URA VALUES) on CMS's Medicaid web site. By doing so, outside concerns, such as First Data Bank, can go to the CMS Medicaid web site, download the quarterly file and compare its similar field values to those listed on the CMS file. Fields such as: DESI Code, Date Entered Market, Therapeutic Equivalency Code, Unit Type, etc., are all used by both systems and should be the same value. If they are different, the bottom line is that the values on the CMS file are correct and should be used when working with the drug rebate system.

PRODUCT DATA
AND
REPORTING REQUIREMENTS

When a labeler requests, and receives, a Medicaid Drug Rebate Agreement from CMS, several forms/record layouts are included so the labeler has the data field and record layout information needed to submit Baseline and quarterly pricing data. The OMB approved form required for reporting pricing data is form 367. A copy of this form and its specific data requirements are provided in this section.

Within 30 days after the quarter the labeler submits its signed rebate agreement to CMS, the labeler is required to supply Baseline data on <u>ALL</u> its existing covered NDCs.

FOR EACH QUARTER THEREAFTER, pricing data is due <u>within 30 days</u> after the quarter is concluded.

Along with the quarterly pricing data, labelers must submit Baseline and quarterly pricing data for any <u>new products</u> from the day they were made available for sale in that quarter, plus any prior quarter's AMP/BP corrections, and Baseline information changes.
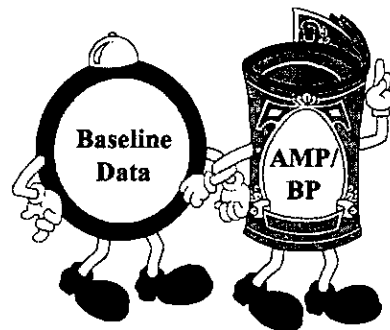
There always seems to be some confusion, especially with new labelers, on the difference between Baseline data and Pricing data. Hopefully, the following will make it clear.

Baseline data is information about a product that CMS needs to calculate rebates (and determine drug coverage). In other words, Baseline data is a profile of the product. EVERY NDC that is paid as an outpatient drug, including separate baseline records for multiple package sizes, is to be submitted with ALL pertinent Baseline data included. Baseline data fields include:

❶	NDC Number
❷	Drug Category
❸	Therapeutic Equivalency Code
❹	DESI Indicator
❺	Date Entered Market
❻	Unit Type
❼	Units Per Package Size
❽	FDA Approval Date
❾	Product Name
❿	Drug Type

Baseline Update Fields

❶	Correction Flag
❷	Termination Date

✎ **NOTE:** **Baseline AMP is a field that is required for "S" and "I" (Single-Source and Innovator) drugs having a Market Date PRIOR TO 10-01-93 only. All "S" and "I" drugs having a Market Date EQUAL TO OR GREATER THAN 10-01-93 and all "N" drugs do not require Baseline AMP reporting.**

BASELINE DATA FIELDS - DEFINED

- **NDC }** The entire reporting system is geared to the product's NDC. This code is broken into three distinct parts:

  ✛ NDC 1 is the 5-digit "labeler" code **assigned to labelers by the FDA.**

  ✛ NDC 2, the second part of the NDC, is the 4-digit number **assigned by labelers** to their products.

  ✛ NDC 3 is the last 2-digit part that **labelers assign** to the package size(s) of a product.

- **Drug Category** is a 1-digit code designating whether a product is classified as Single-Source (S), Innovator Multiple-Source (I), or Non-Innovator Multiple-Source (N).

- **Therapeutic Equivalence Code** is a 2-digit code that begins either with an "A" (therapeutically equivalent to other products), a "B" (NOT therapeutically equivalent to any other drug), or contains the 2-digit "NR" (not rated) rating. Products are considered equivalent **IF** they contain the same active ingredients, are of the same dosage form, and are identical in strength.

- **DESI** (Drug Efficacy Study Implementation) drugs are those which lack substantial evidence of effectiveness, i.e., less than effective and are subject by the FDA to a Notice of Opportunity for Hearing. DESI codes have values of "2" through "6." Drugs listed with DESI code values of "2", "3", or "4" are rebatable. Those listed with DESI code values of "5" or "6" are not rebatable.

- **Date Entered Market and FDA Approval Date** MUST both be included for Baseline data. The FDA Date must be equal to or less (older) than the Market Date. Market Date is the date the product was first offered for sale. FDA Date is the date of FDA Approval. If the product is an over the counter that does not need an FDA Date, the Monograph date is used in its place. If the product is a NEW PACKAGE SIZE of an existing product, **DATES MUST** reflect the original product.

- **Unit Type and Units Per Package Size** (UPPS) must be developed together in order to work correctly in the system. There are 7 specific Unit Type values plus "EA" (each) for certain types of products. The Unit Type **MUST BE** designated as the smallest unit for which the product can be sold. This is what ALL PRICING is based on. AMP, BP and (where required) Baseline AMP reflect the price of ONE OF THE APPROPRIATE UNIT TYPE. Thus, if the Unit Type is "ML," pricing reflects ONE ML. The UPPS value depends on whether the package can be broken and dispensed in smaller amounts. An example is a product with a Unit Type of "CAP" (capsule). If the product comes in a bottle of 100 CAPs that MUST be dispensed as is, the UPPS equals 100. If, however, the product comes in a bottle of 100 that a pharmacist may open and dispense 10, 20, 50, etc., CAPs at a time, the UPPS is equal to 1. In ALL cases, the prices reflect 1 capsule. This is one of the few conditions where a data field (in this case, UPPS) can contain different values for different package sizes of a given product. In most cases, the data field information is the same across all package sizes. UPPS, however, can equal 1 for one package size and 100 for another. A further detailed discussion of UPPS is provided later in this section.

- **Product Name** is the name the product is listed under with the FDA. There are up to 63 characters allowed for this field.

- **Drug Type** is a 1-position field that contains a "1" if the product is a Rx and a "2" if it is an OTC.

- **Correction Flag** is "1" if data sent previously are being corrected, otherwise, it is left blank. THIS FIELD IS USED ONLY FOR UPDATING EXISTING BASELINE AND/OR PRICING DATA.

- **Termination Date** is determined by the reason the product is being discontinued. If it is being pulled from the shelf immediately, due to a health or safety reason, whether it be by FDA or labeler directive, the Termination Date is the date it is removed. If, however, it is being replaced by an improved version, or discontinued, the Termination Date is the shelf life of the last batch sold. <u>THE TERMINATION DATE IS LEFT BLANK UNLESS AND UNTIL ONE OF THE ABOVE CONDITIONS OCCURS.</u>

In **all** cases, labelers are required to submit prices to CMS for FOUR QUARTERS BEYOND the termination date. The last calculated AMP, and where applicable, BP, are to be reported each quarter for this time period, with one exception. This exception is when a product has several package sizes and at least one is being terminated. The AMP/BP calculations for the **active** package sizes are to be done normally. These same active calculated AMP/BP values are to be reported for the terminated package size for four quarters beyond the termination date.

Pricing data consists of:

✓ the AMP for EACH NDC; and
✓ BP for all "S" and "I" NDCs.

This data is due within 30 days after the end of a calendar quarter.

Pricing data fields include:

❶ Reporting quarter and year (QYYYY);
❷ NDC;
❸ AMP; and
❹ BP (for "S" and "I" NDCs).

F7

LABELER QUARTERLY PRICING DATA
PAPER REPORTING FORMAT

QUARTERLY REPORT FOR ___/_____
                Q YYYY
                                  LABELER CODE _____

PRODUCT CODE: __ __ __ __   PACKAGE SIZE CODE: __ __

DRUG CATEGORY: __
THERAPEUTIC EQIV. CODE: __ __
DESI INDICATOR: __
AVERAGE MANUFACTURER PRICE: __ __ __ __ __ . __ __ __ __ __
BEST PRICE: __ __ __ __ __ . __ __ __ __ __
DATE ENTERED MARKET: __ __ __ __ __ __ __ __
BASELINE AMP: __ __ __ __ __ . __ __ __ __ __
TERMINATION DATE: __ __ __ __ __ __ __ __
CORRECTION FLAG: __ (Activate for Baseline Data and/or Pricing Data corrections.)
UNIT TYPE: __ __ __
UNITS PER PACKAGE SIZE: __ __ __ __ __ __ __ . __ __ __
FDA APPROVAL DATE: __ __ __ __ __ __ __ __
DRUG TYPE: __
PRODUCT NAME: __

__ __

__ __ __ __ __ __
****

PRODUCT CODE: __ __ __ __   PACKAGE SIZE CODE: __ __

DRUG CATEGORY: __
THERAPEUTIC EQIV. CODE: __ __
DESI INDICATOR: __
AVERAGE MANUFACTURER PRICE: __ __ __ __ __ . __ __ __ __ __
BEST PRICE: __ __ __ __ __ . __ __ __ __ __
DATE ENTERED MARKET: __ __ __ __ __ __ __ __
BASELINE AMP: __ __ __ __ __ . __ __ __ __ __
TERMINATION DATE: __ __ __ __ __ __ __ __
CORRECTION FLAG: __ (Activate for Baseline Data and/or Pricing Data corrections.)
UNIT TYPE: __ __ __
UNITS PER PACKAGE SIZE: __ __ __ __ __ __ __ . __ __ __
FDA APPROVAL DATE: __ __ __ __ __ __ __ __
DRUG TYPE: __
PRODUCT NAME: __

__ __

__ __ __ __ __ __

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM CMS-367)

:::

DATA ELEMENT NAME: Labeler Code - First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug. Numeric values only, 5 digit field, right justified and 0-filled for 4 digit labeler codes.

:::

DATA ELEMENT NAME: Product Code - Second segment of National Drug Code. Numeric values only, 4 digit field, right justified, 0-filled.

:::

DATA ELEMENT NAME: Package Size Code - Third segment of National Drug Code. Two digit field, right justified, 0-filled.

:::

DATA ELEMENT NAME: Period Covered - Calendar quarter and year covered by data submission. Numeric 5 digit field, QYYYY.
Valid values for Q:
    1 = January 1 - March 31
    2 = April 1 - June 30
    3 = July 1 - September 30
    4 = October 1 - December 31

Valid values for YYYY: Four digit calendar year covered.

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MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM CMS-367)

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DATA ELEMENT NAME: Product Registration Name - Product name as it appears on FDA registration form. Alpha-numeric values, 63 characters, left justified.

:::

DATA ELEMENT NAME: Drug Category - Classification of drug for purposes of rebate calculations. Alpha-numeric values, 1 character.
Valid values:
        N = Non-innovator multiple source
        S = Single source
        I = Innovator multiple source

:::

DATA ELEMENT NAME: DESI Drug Indicator - A DESI drug is any drug that lacks substantial evidence of effectiveness (less than effective (LTE)) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs. Numeric value, 1 digit.

Valid values:
2 = Safe and effective or non-DESI drug
3 = Drug under review (no NOOH issued)
4 = LTE/IRS drug for SOME indications
5 = LTE/IRS drug for ALL indications
6 = LTE/IRS drug withdrawn from market

:::

F7c

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM CMS-367)

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DATA ELEMENT NAME: Therapeutic Equivalence Code - The classification as contained in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made. Alpha-numeric values, 2 character field.

Valid values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

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F7d

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM CMS-367)

:::

DATA ELEMENT NAME: Unit Type - Basic measurement that represents the smallest unit by which the drug is normally measured. The rebate amount will be calculated per unit. Alpha-numeric values, 3 character field, left justified.
Valid values:

AHF =   refers only to injectable Anti-Hemophilic Factor (AHF) units

CAP =   Capsule

SUP =   Suppository

GM =   Gram

ML =   Milliliter

TAB =   Tablet

TDP =   Transdermal Patch

EA =   EACH (Refers to drugs not identifiable by any other unit type as given in program instructions.)

:::

DATA ELEMENT NAME: Units Per Package Size Code - Total number of units, as defined in the Unit Type field, in the smallest dispensable container or entity for the product defined by the full NDC. Numeric values, 10 digit field: 7 whole numbers and 3 decimal places.

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F7e

::

DATA ELEMENT NAME: AMP (Average Manufacturer's Price) -
The AMP per unit <u>per product code only</u> for the period covered, based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.

::

DATA ELEMENT NAME: Baseline AMP - The Average Manufacturer's Price per unit <u>per product code</u>. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes.

For <u>ALL</u> "S" and "I" drugs marketed <u>AFTER</u> 09-30-90, <u>REGARDLESS OF FDA APPROVAL DATE</u>, the Baseline AMP is determined by the AMP for the first day of the first full month in which the drug was first marketed. **<u>NOTE:</u> Effective for all quarters beginning with 10-01-93, the Baseline AMP for these products is to be reported as "0", and is subsequently determined by the AMP for the first full quarter <u>AFTER</u> the product is marketed.**

Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places and round to 6 decimal places. Zero fill for Non-innovator Multiple Source drugs.

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM CMS-367)

DATA ELEMENT NAME: Best Price - The lowest price the product was sold for by the labeler for the quarter to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices of any agency of the Federal Government). Effective 10/01/92, manufacturers must exclude any prices charged to the following entities: the Indian Health Service; the Department of Veterans Affairs; a State home receiving funds under section 1741 of title 38, United States Code; the Department of Defense; the Public Health Service (PHS) or any entity described in section 340B(a)(4) of the PHS Act and as further specified in Federal Register notices; the Federal Supply Schedule; and, a State pharmaceutical assistance program. **The Best Price is the lowest price, regardless of package size, for the same product code.**

Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places. Zero fill for Non-innovator-Multiple Source drugs.

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM CMS-367)

DATA ELEMENT NAME: FDA Approval Date - Date of FDA approval of the NDA, without regard to whether the drug has been sold or transferred to any entity, including a subsidiary or division of the original manufacturer. For OTC drugs, use Monograph date. Numeric values, 8 digit field, (MMDDYYYY).

DATA ELEMENT NAME: Date Entered Market - If marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed. Numeric values, 8 digit field, (MMDDYYYY).

DATA ELEMENT NAME: Drug Termination Date - Date drug was withdrawn from market or shelf life of last lot sold if no longer distributed by labeler. Numeric values, 8 digit field, (MMDDYYYY).

DATA ELEMENT NAME: Drug Type Indicator - Indicator to show whether this drug product can be acquired only by prescription or can be acquired OTC. Numeric value, 1 digit field.
Valid values: 1 = Rx
                  2 = OTC

DATA ELEMENT NAME: Correction Record Flag - Indicator that this record corrects and replaces a record already submitted for the initial submission. Numeric value, 1 digit field.
Valid values: 0 = Original record
                  1 = Correction record

F7h

DATA REPORTING

Baseline (product) and Pricing data can be submitted in one of three ways. When the Drug Rebate Agreement is signed, labelers are given three data transmission options to choose from:

1. **Electronic** data submission can be done by setting up a contract with Sterling Commerce for an electronic mailbox. CMS supplies the telephone number, record layouts, and instructions for getting started.
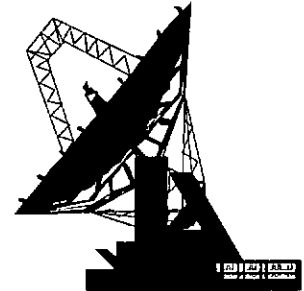
2. **A PC, windows-based application** is provided by CMS free of charge for those electing this option. CMS maintains this application, updates it as required, and includes an instructional guide.
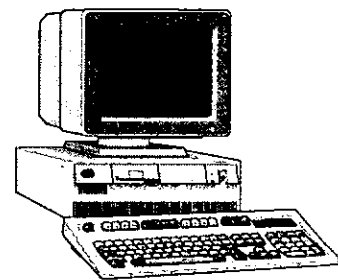
3. For small companies, **paper** submission can be sent/faxed on the required form 367. **This method is reserved for companies having 5 or fewer NDCs.**

Data correction reporting requirements are different for Pricing data and for Baseline data.

➤ For pricing (AMP/BP) corrections the required fields are:

1. NDC
2. Quarter Affected
3. Correct AMP/BP
4. Correction Flag (set to "1")

➤ For Baseline changes/corrections: ALL fields, except AMP/BP, are required.

❧NOTE: Fields not corrected are reported with current values. Corrected fields contain new field values. Submitting Baseline changes with only the affected field(s) will result in the record being rejected by the edit program.

Don't Be Late **REPORTING DEADLINES**

Pricing data and, when needed, Baseline data are due to CMS within **30 days after the end of each calendar quarter** as shown below.

QUARTER	DUE DATE
January-March	April 30
April-June	July 30
July-September	October 30
October-December	January 30

Data not submitted timely could affect several things. First, the labeler may not have time to respond to edit reports for rejected data. CMS maintains an edit program through which ALL data is run and sends edit reports for

rejected data records to labelers as quickly as possible for correction. If the labeler returns corrected data before the deadline, it is included in CMS's quarterly URA calculation on the state tape. If the corrected data are not sent to CMS on time, the URA for affected NDCs are not included on the state tape that quarter. (The URA will, however, be included on the tape sent to states the following quarter.)

Second, <u>EXCLUDING UNTIMELY DATA MAKES LABELERS RESPONSIBLE FOR CALCULATING THEIR OWN UNIT REBATE AMOUNTS AND REMITTING THE APPROPRIATE REBATE TO THE STATE</u>.

Third, if a labeler fails to submit data for two consecutive quarters, CMS sends a termination letter. Unless missing data is submitted within the letter's specified timeframe, the labeler's rebate agreement <u>WILL BE TERMINATED</u>. ☹

<u>No Price Changes? You Must Still Report Pricing!</u>

One frequent question labelers ask: **Are labelers required to report the same pricing data quarter after quarter, even when their prices haven't changed?** The answer: **Yes!**

In addition to the statutory requirement, the most important reason for continuous price reporting relates to the AMP calculation. Because AMP is a sales/units calculation, it **is** possible for pricing to change even though labeler prices do not change.

For example, if a labeler applies a large volume of discounts one quarter, but not in other quarters, two consecutive quarters could have the <u>same exact</u> sales but <u>the NET dollars are different and the NET units are the same</u>. In this example, current AMP will differ from last quarter's AMP even though the labeler's price remains the same.

Due to variables affecting AMP and the statutory requirement to submit quarterly pricing, a labeler's failure to comply with quarterly pricing reporting requirements will result in a violation of the rebate agreement. (See section L of this guide for information on penalties for failure to submit pricing data.)

BUYING/SELLING PRODUCTS

The following paragraphs explain different situations of buying and selling products from one company to another and the responsibilities of each party under the drug rebate program. Please keep in mind that CMS does not mandate any requirements regarding the sale or purchase of products between companies. However, the information provided here may be helpful when considering an agreement to sell/purchase products.

Buying a Product - But Not Changing the NDC

When a company buys a product but does not change the NDC, the company that holds title to the labeler code of the product is ultimately responsible for reporting pricing and paying rebates. However, either company can send CMS pricing data for the product and can pay the rebates to states.   State invoices and CMS edit reports, etc., will be sent to the holder of the labeler code because CMS's data base only accommodates one contact per labeler code.

Also, **product history (Baseline data) does not change** with the sale of this product. It follows the NDA/ANDA and **not** the NDC.

Buying a Product - But Changing the NDC

When a company buys a product and changes the NDC to be their own, the previous owner is responsible for supplying CMS with a termination date equal to the shelf life of the last lot sold under the old NDC. The previous owner is also responsible for reporting pricing data on that product for 4 quarters beyond the termination date. The new owner of the product is solely responsible for reporting pricing data starting with the quarter the product is for sale under the new NDC. It is the purchasing labeler's responsibility to get the drug history from the labeler selling the drug. However, it is acceptable for either company to report pricing data for the old NDC for 4 quarters past the termination date.

As in the previous situation, the **product history does not change.** It stays with the product and is duplicated for the new NDC.

F10a

Buying a Product and Changing Its Makeup

If a company buys a product and changes the product (tablet to capsule, shape, formula, etc.,) and receives approval for an ANDA, the NDC that reflects the product under the new ANDA **requires history of its own,** i.e., Baseline data. Baseline data and pricing data should be reported by the new company and should reflect dates, etc., of the product under the new ANDA, **not** under the old NDA/ANDA. The previous owner is responsible for reporting pricing data for the old NDC and for supplying a termination date (shelf life of the last batch sold). The previous owner is also responsible for reporting pricing data for 4 quarters beyond the termination date.

F10b

Multiple Package Size Products and Data Requirements

Baseline Data Fields – 9-digit NDC (same for all package sizes):

1. Drug Category
2. Therapeutic Equivalence Code
3. DESI Indicator
4. Date Entered Market
5. Unit Type
6. FDA Approval Date
7. Drug Type
8. Baseline AMP (for S & I drugs marketed before 10/1/1993)

Baseline Data Fields – 11-digit NDC (unique to each package size):

1. NDC 3
2. UPPS
3. Product Name
4. Termination Date

Quarterly Pricing Data (same for all package sizes):

1. AMP (weighted)
2. BP (for S & I drugs)

Facts regarding multiple package size products:

- As new package sizes are added, pricing data and URAs are back-filled with the information from the oldest marketed package size for uniformity of data.

- Common baseline data fields (shown above) for multiple package size products will be automatically aligned with the information from the oldest marketed package size.

- Pricing changes affect ALL package sizes due to weighting. Changes to Date Entered Market and/or Baseline AMP will cause all package sizes to recalculate.

- Individual records for package sizes will not be allowed. There will be one common record for each prodcut and one pricing (history) record for each package size.

CALCULATING AMP

There's no magic to this process, just a little math. Read the next few paragraphs and you'll be an expert.

Basically, AMP is calculated as NET quarterly sales divided by the number of units sold.

"Net quarterly sales" are derived **after** all required adjustments are made (e.g., discounts, rebate for state-only programs, breakage, etc.). Total units sold must be adjusted for returns, charge backs, etc.

AMP Calculation – Multiple Package Sizes of a Product

If there are multiple package sizes of a product (NDC 1 and NDC 2 are the same but NDC 3 is different), one **"weighted AMP"** is used. Total units sold for all package sizes are divided into total net sales dollars for all package sizes to arrive at the weighted AMP. The weighted AMP is used for all records of the same product.

All pricing is calculated by the **Unit Type** as input by the labeler with the product's Baseline data. For example, if a product is listed with a Unit Type of ML, **all** pricing must be on a per ML basis. If the product is sold in a 30 ML tube, the pricing must be shown as the price of one ML, not 30 ML. (See other portions of this section for discussions on Unit Type and UPPS.)

BEST PRICE (for "S" and "I" Drugs Only)

BP is the lowest price at which the product is sold during a rebate quarter regardless of package size. Like AMP, BP is the same across all package sizes of a product; however, it is not a weighted value.

MISCELLANEOUS AMP/BP ISSUES

*   BP greater than AMP: Discounts, returns, seasonal sales, etc., occasionally cause AMP to calculate lower than BP. On these occasions, always report BP as equal to the calculated AMP. CMS sends a report to the labeler for a corrected pricing submission in any instance of BP reported as greater than AMP. (See section G for more information on this issue.)

* Zero or Negative AMP: Numerous adjustments in a quarter occasionally cause AMP to calculate as zero or a negative value; however, **do not** submit a zero or negative AMP to CMS. Submit the last valid AMP on record (i.e., last quarter's AMP) for the product.

* No Sales in a Quarter: If there are no sales for a product in the quarter, use the last quarter's AMP (and BP for S and I drugs, if required).

* No Sales in First Quarter Marketed: Labelers are required to report AMP for the first quarter the product is on the market (as well as BP for "S" and "I" drugs). If no units were sold during this quarter, the labeler uses the sales price of the product (i.e., the price the product was either offered for sale or would have been sold for during the quarter).

Bundled Sales

As defined in the Medicaid Drug Rebate Agreement: " 'Bundled Sale' refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."

The key to identifying a bundled sale is that the sale is <u>contingent</u> upon an additional purchase requirement(s) of the retail purchaser (e.g., pharmacies, beneficiaries, etc.).

Example A: Buy one bottle of pills and get the second bottle for 50% off.

In this example, the 50% "free" product is contingent upon purchase of one and a half bottles of pills, so it is not considered to be free.

Example B: Buy one tablet and get a bottle of cream free.

In this example, the cream is not considered to be free because it is contingent upon the purchase of the tablet.

Example C: A labeler provides all pharmacies that purchase their drug product with 250 units of extra drug product for free. Patients get prescriptions from their doctors to redeem at pharmacies for the free drug product samples.

In this example, only pharmacies that purchase the labeler's drug product are eligible for the "free" drug product; therefore, the extra drug product is not considered to be free.

Example D: A newspaper advertisement instructs interested parties to call a toll-free number to receive a labeler's free sample drug product. The caller is mailed a free sample of the drug product.

In this example, the drug product is not contingent upon a purchase requirement, and is therefore considered to be free.

Bundled Sales will affect the AMP and BP calculations. The discounted or contingent drug product's value is proportionately distributed among the other drug products in the bundle. Follow the two steps below to accomplish correct bundled sales pricing.

❶ Determine the value of the contingent drug product by determining its AMP for the same quarter if it were sold alone. This value is considered a discount and is proportionately distributed to the other drug products within the bundle.

❷ Refigure the AMP/BP of the drug products within the bundled sale by applying the value of the discounted/contingent drug product proportionately among the other drug products.

F11b

An example of the AMP and BP calculation in a bundled sales situation is offered below.

THE DEAL

Buy the first two drug products, get the 3rd drug product "free!" (By now you know the 3rd drug product is not considered a free drug product in the Medicaid Drug Rebate Program; rather, it is a contingent drug product.)

1. Calculate "Unbundled" AMP

Drug Product 1: net sales = 100 TAB for $100 = $1.00 AMP per TAB
Drug Product 2: net sales = 100 ML for $200 = $2.00 AMP per ML
Drug Product 3: net sales = 100 GM for $10 = $.10 AMP per GM

The total selling price for these "unbundled" products is $310 ($100 + $200 + $10). By discounting the contingent or 3rd drug product by purchasing the first two drug products, the sales amount decreases by $10 to $300 ($310 - $10). Divide the discounted amount ($300) by the total selling price ($310), then subtract that percentage (97%) from 100% to derive the discount percentage (3%). Apply a discount of 3% to each drug product's selling price in order to calculate the revised AMP.

2. The "Revised" AMP

Drug Product 1: $100 x 3% = $3.00 discount
Drug Product 2: $200 x 3% = $6.00 discount
Drug Product 3: $10 x 3% = $.30 discount

Drug Product 1: $100 - $3.00 = $97.00 for 100 TAB = .97 AMP*
Drug Product 2: $200 - $6.00 = $194.00 for 100 ML = 1.94 AMP*
Drug Product 3: $10 - $.30 = $9.70 for 100 GM = .097 AMP*

*   Since the revised AMP figure includes a discount, it must be applied against other discounted selling prices to determine the drug product's lowest price or BP.

✎NOTE: Valid bundled sales only include drug products that meet the definition of a covered outpatient drug as defined in the drug rebate agreement and statute. If a non-drug product (e.g., lip balm, tissues, etc.) is included in the bundled sale it is not eligible for inclusion in the Medicaid Drug Rebate Program.
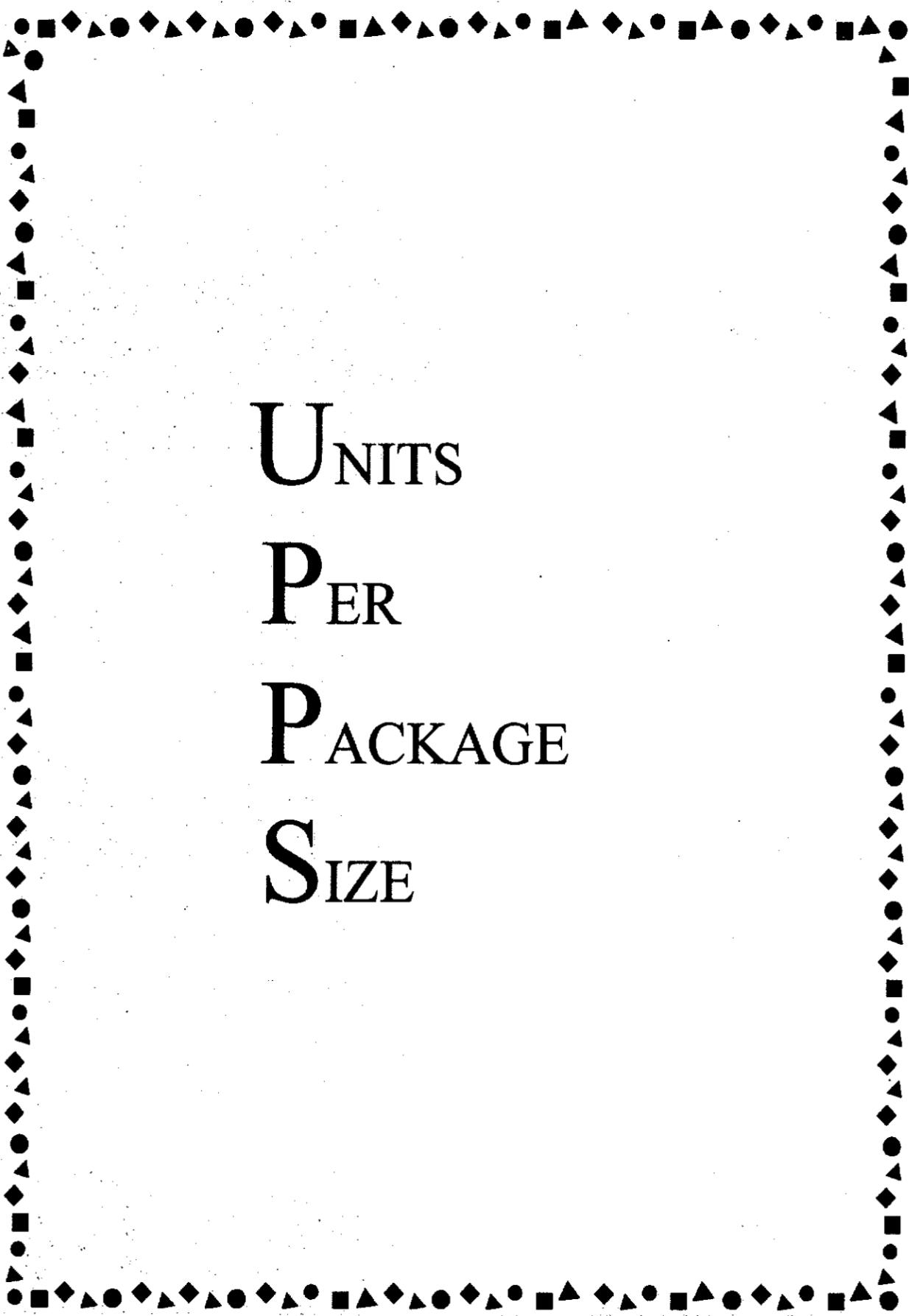
U<small>NITS</small>

P<small>ER</small>

P<small>ACKAGE</small>

S<small>IZE</small>

UNITS PER PACKAGE SIZE (UPPS)
HOW, WHEN AND WHY

The UPPS field was designed for maximum accuracy when states report "unbreakable" package utilization to labelers. If a package *can be* broken by a pharmacist to dispense fewer units than the package contains, the UPPS value is "1." If a package *cannot* be broken, the UPPS value is the *actual unit value* of the package.

Over-the-counter products usually fall into the *unbreakable* package category, with few exceptions.

The ability to break packages of prescription drugs varies based on the product and package size.

Prescription drug examples that are generally *unbreakable* packages include blister packs, birth control pills, inhalers, and ointment tubes.

Prescription drug examples that are generally *breakable*, or capable of being dispensed in smaller amounts than the original package size, include tablets, capsules and liquid medication in large bottles.
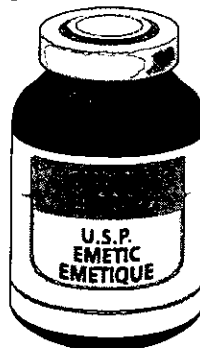
CMS Data vs. 3rd Party Data - General

Reimbursement: Most states use 3rd Party Data Companies for their drug **reimbursement** activities, so labelers generally report their product and pricing data to these data vendors in the format required by the companies. CMS does not use this information for the Medicaid Drug Rebate Program.

Rebate: For **rebate** purposes, however, labelers must use <u>only</u> CMS data fields to report product and pricing data to CMS. CMS supplies data to states which must use the CMS data for Medicaid Drug Rebate Program transactions with labelers and CMS.

Note to States: Although some data vendors download CMS data from our website and may include this with their data, it is not valid for purposes of the Medicaid Drug Rebate Program. Only data sent directly by CMS to states via the quarterly URA tape are valid.

Note to Labelers: Similarly, labelers editing their data must make changes to the CMS data separately from any edits supplied to data vendors as CMS does not have any relationship or data sharing agreement with these companies.

CMS Data vs. 3rd Party Data – UPPS

The reason for the CMS data requirement rather than 3rd party data use is evident for all data fields, including the UPPS field. Labelers and states cause confusion, disputes, and extra work when they stray from this requirement.

Labelers: All pricing calculations for products are based on the UPPS value the labeler uses. There is no absolute rule when converting milliliters and grams to ounces. Some labelers use the exact equivalence, while others use the recognized rounded value of 30. CMS does not require labelers to use either method, but does require labelers to remain consistent in the method they choose. So, if labelers choose 30 for the ML to OZ conversion, they must always use this method.

States: State use of the UPPS field supplied by CMS from the quarterly URA tape to calculate its total utilization is **imperative**. States calculate total NDC utilization of unbreakable packages by multiplying UPPS by total prescriptions of the NDC. If the state uses a data vendor's UPPS field, the value may differ from the UPPS the labeler reports to CMS causing invalid units on the invoice and ultimately resulting in disputes. Disputes caused by state use of non-CMS data fields, including UPPS, will always be resolved in favor of the labeler. (See section K for information on the Dispute Resolution Program.)

STATE
INVOICE

STATE INVOICE

UTILIZATION DATA REPORTING REQUIREMENTS

Statute requires states to report quarterly drug utilization data to labelers participating in the drug rebate program **not later than 60 days** after each rebate period. States are also required to transmit a copy of this quarterly utilization data report to CMS. (Utilization adjustment data for prior rebate periods are discussed later in this section.)

The law requires the Secretary to establish the format for this data submittal. The Secretary delegated the establishment of the reporting format to CMS. In 1991, the former Health Care Financing Administration and State Medicaid agency representatives developed the State Invoice (form CMS-R-144) to report utilization data to labelers. OMB approved the invoice format and CMS mandates it use. This section contains form CMS-R-144, along with the electronic format and definition of each data element required.

For each covered outpatient drug dispensed **AND** PAID FOR BY THE STATE, the invoice specifically requires reporting the following for **EACH** NDC number listed by the state.

1. State Code
2. Period Covered
3. Labeler Code
4. Product Code
5. Package Size Code
6. Product FDA Registration Name
7. Rebate Amount Per Unit
8. Total Units Reimbursed
9. Total Rebate Amount Claimed
10. Number of Prescriptions
11. Total Amount Reimbursed by the State
12. Correction Record Flag

Please remember that the utilization data reported on the invoice MUST be based on the payment date NOT on the date dispensed.

Invoices must reflect only NDCs paid for, in whole or in part, under the Medicaid program.

Invoices MUST NOT REFLECT any NDCs paid for under:

1. **A state-funded only General Assistance program;**
2. **Other state-funded only programs; or**
3. **Other Federal drug rebate programs.**

Invoices containing units for NDCs excluded from the Medicaid Drug Rebate Program cause delayed processing by labelers.

♣ **CLARIFIER:** Portions of this section contain references to URA and RPU. These terms are synonymous in the drug rebate program. URA is mostly used by CMS when referring to the field on the state tape containing the unit rebate amount. RPU is used mainly by states and labelers when referring to the field on the Invoice, ROSI, and PQAS containing the rebate per unit. ♣

INVOICING ZERO URAs

The CMS state tape contains zero URAs for several reasons relative to the various pricing data edit reports. These reports are fully detailed in section G of this guide.

STATE INVOICES **MUST INCLUDE** UTILIZATION DATA FOR THESE NDCS AND REPORT THE RPU AS ZERO.

Most NDCs rejected by the drug rebate edit program contain errors. Pricing errors that cause zero RPUs on the state invoice require labelers to calculate the correct RPU and pay the rebate. The labeler must report the correct AMP/BP to CMS by the next quarter's data submission deadline.

CMS's next quarterly state tape contains the old and the corrected URAs for prior quarters based on labelers' submission of corrected pricing data.

TOLERANCE THRESHOLD

States may apply a $50 tolerance threshold per labeler to its current quarter invoice. This $50 tolerance threshold may also be applied to utilization changes for any quarter's invoice.

States may invoice labelers for amounts at or below the tolerance level. States applying the tolerance should report the quarter, number of units, and NDC(s) affected to the labeler.

If the tolerance is applied, states must maintain documentation which clearly identifies the labeler code, the NDC number, the applicable quarter, and the amount to which the tolerance is applied. Additionally, states which apply the tolerance level **will not be at risk** for loss of Federal financial participation for amounts at or below the tolerance. (The tolerance threshold for interest is discussed in section I of this guide.)
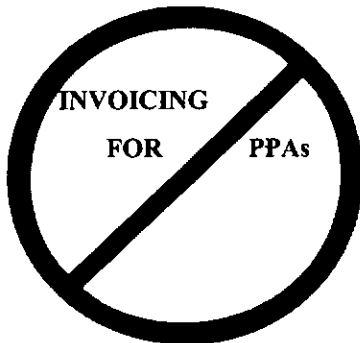
The practice of states invoicing for PPAs is no longer permitted. CMS's August, 1995 decision to shift the PPA responsibility from the states to the labelers is in keeping with the intent of the Federal statute which requires labelers to remit rebate payments to states using accurate pricing data.

States may opt to attach a PPA listing to their current quarter invoice for informational purposes only. The dollar amounts associated with PPAs are not to be included on the invoice.

> ✎ **NOTE:** Labelers are not obligated to respond to PPAs incorporated into the state's invoices.

Section J of this guide explains the current PPA process and the PPA verification method for both states and labelers.

SENDING UTILIZATION DATA

☞ **TO LABELERS**

Although the state invoice format is mandated, the reporting media states use to submit their invoices to labelers is not mandated. States can transmit invoices to labelers using electronic media, diskette, or paper.

The lack of mandated reporting media has been a source of discussion since the program began. CMS cannot mandate the media states use to report utilization data to labelers because over 500 labelers participate in the program and use various types of data systems.

State agencies also use various data systems, many of which are not compatible with labelers' systems. CMS encourages state use of electronic media.

States should send invoices to the labeler's invoice contact. The state quarterly URA tape includes an updated labeler contact list. This file is the second data set on the quarterly tape. States should use the correct contact/address to submit the invoice. CMS instructs labelers to send all contact changes timely.

SENDING UTILIZATION DATA (Cont'd.)

☞ TO CMS

States must report their utilization data to CMS using either a tape or cartridge with an IBM Standard Label. The characteristics of this media are:

- ◆ Data Set Name: RBTE.Qq.Yyyyy.xx
    Where   q = quarter
            yyyy = year
            xx = State postal abbreviation

- ◆ Record Profile: 82 characters, fixed block (FB),
                        9,266 characters per block.

✎NOTE: **If the standards outlined above are not met, THE TAPE WILL NOT BE PROCESSED.**

Send the **tape or cartridge** to: Centers for Medicare & Medicaid Services
Office of Information Systems
Attention: Tape Library
7500 Security Boulevard
Baltimore, Maryland 21244

✎NOTE: When CMS completes its processing of state utilization tapes, the tapes/cartridges are not returned to the states. Likewise, states are not required to return quarterly tapes/cartridges to CMS.

☞ **ONLY ONE (1) UTILIZATION DATA TAPE PER QUARTER IS TO BE SUBMITTED TO CMS.**

SENDING UTILIZATION DATA TO CMS (Cont'd.)

States are required to send a tape confirmation letter indicating the data set name, volume serial number, and the date the tape was sent to CMS. **(A copy of this letter should also be enclosed with the tape/cartridge.)**

Send the confirmation letter to: Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
Mail Stop S3-13-15
7500 Security Boulevard
Baltimore, Maryland 21244

Information from state utilization tapes is used to prepare CMS's annual drug rebate Report to Congress. Therefore, timely submission of these tapes is imperative.

In an effort to eliminate errors that hinder CMS's processing of states' quarterly tapes/cartridges, a checklist was developed for state use. States should make every effort to comply with the checklist.

NOTE: If the standards outlined on the checklist are not met, the CMS tape librarians will not be able to determine that the tapes are drug rebate utilization tapes. All unrecognizable tapes/cartridges are erased by CMS tape library personnel and made available for re-use internally. **THIS WILL CAUSE YOUR UTILIZATION DATA TO BE LOST. RESUBMISSION OF YOUR DATA WILL BE REQUIRED.**

A copy of the checklist is provided on the following page.

MEDICAID DRUG REBATE PROGRAM
STATE UTILIZATION TAPE SUBMISSION CHECKLIST

The CMS tape library receives a large quantity of tapes from many outside sources. To ensure that your tape is received and processed correctly, please follow the checklist below.

____ Assure that the correct naming convention is used for the data set on the tape?

RBTE.Qq.Yyyyy.xx   Where   q = quarter

yyyy = year

xx = State postal abbreviation

DO NOT USE FOREIGN.OPCART.DRqyyyy.xx or
FOREIGN.LOPREEL.Dqyyyy.xx

____ Is there an external label on the tape indicating that it is a drug rebate tape? (A label with a data set name containing RBTE.Qq.Yyyyy.xx is necessary.) If not already there, please include it now.

____ Did you generate a confirmation letter indicating the file name, volume serial number, and the date the tape was sent? If not, please do so now. This letter is sent to the following address:

Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
Mail Stop S3-13-15
7500 Security Boulevard
Baltimore, Maryland 21244

____ Please enclose a copy of the confirmation letter with the tape/cartridge.

____ Please assure that the tape/cartridge is addressed as follows:

Centers for Medicare & Medicaid Services
Office of Information Systems
Attention: Tape Library
7500 Security Boulevard
Baltimore, Maryland 21244

____ If you re-used a CMS tape, YOU MUST REMOVE OR OBLITERATE ALL OF CMS'S EXTERNAL LABELS AND PLACE A NEW LABEL ON THE TAPE/CARTRIDGE; otherwise, the tape/cartridge will be returned to blank stock and your data will not get processed. This will require a resubmission of your data.

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REPORTING UTILIZATION CHANGES

☞ TO LABELERS

States must submit utilization changes to labelers for individual NDCs when there are changes to:

- the total units reimbursed.

CMS encourages states to send labelers utilization-related changes affecting:

- the number of prescriptions; and/or
- the total reimbursement amount.

Changes are reported with current quarter utilization data, **BUT NOT** on the same invoice pages as current quarter data. STATES MUST REPORT UTILIZATION CHANGES TO LABELERS USING A SEPARATE INVOICE PAGE FOR **EACH** QUARTER CHANGES OCCURRED. States sending invoice pages representing multiple quarters delay invoice processing.

Delayed invoice processing is also caused by states that use inconsistent utilization change reporting methods. States must initially notify labelers of the method used to report utilization changes. States may completely overlay previously reported data, or may report just the addition or subtraction to previously reported data. Whichever method is chosen, consistency from quarter to quarter is the primary factor. If the state's method of reporting utilization changes is revised, States may use the short form developed by CMS to notify labelers. This form is provided on the following page.

Medicaid Drug Rebate Program

State Notification to Labelers of Method Used
for Reporting Utilization Changes

TO (Labeler):

FROM (State):

DATE:

Changes to utilization data are reported to you as:

☐   An overlay (replacement) of previously reported units.

☐   A plus or minus to the units previously reported.

REPORTING UTILIZATION CHANGES (Cont'd.)

☞ **TO CMS**

States must submit changes to the total units reimbursed, the number of prescriptions, or the total reimbursement amount. These utilization changes must be included on the data tape containing the current quarter utilization.

DON'T FORGET   Only one tape per quarter is permitted.

CMS uses the state correction records as a **replacement** for a record submitted in a prior quarter.

For each correction record sent to CMS, the state must ensure that:

1. The correction flag = "1"; and
2. QYYYY = the calendar quarter and 4-digit year being corrected. (This is never the current calendar quarter/year.)

DATE: ___/___/_____ STATE OF _____ PAGE ___ OF ___
      MM DD YYYY _____ (Medicaid Agency)

Source: State Agencies
Target: Manufacturers   **MEDICAID DRUG REBATE INVOICE**

Manufacturer: _____ STATE CODE: ____ INVOICE NO.: _____
Address: _____ PERIOD COVERED: _____(QYYYY)

City: _____ State: ____ Zip: _____

NDC Number	Drug Name	Rebate Amount Per Unit	Total Units Reimbursed	Total Rebate Amt. Claimed	No. of Scripts	Total Reimb. Amount	Corr Flag
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___
_____	_____	_____	_____	_____	_____	_____	___

TOTALS: *

Note: NDC# = Labeler Code (5#s)   *Please remit this amount to: _____ (Medicaid Agency)
           Product Code (4#s)   Address:
           Pkg. Size Code (2#s)

MEDICAID DRUG REBATE PROGRAM
RECORD FORMAT
STATE INVOICE/UTILIZATION RECORD
(FORM CMS-R-144)

Source: State Agencies
Target: CMS and Manufacturers

FIELD	SIZE	POSITION	REMARKS
Record ID	4	1 - 4	Constant of "01"
State Code	2	5 - 6	P.O. Abbreviation
Labeler Code	5	7 - 11	NDC #1
Product Code	4	12 - 15	NDC #2
Package Size Code	2	16 - 17	NDC #3
Period Covered	5	18 - 22	QYYYY
Product FDA Registration Name	10	23 - 32	
Rebate Amount Per Unit	11	33 - 43	99999V999999
Total Units Reimbursed	12	44 - 55	999999999V999
Total Rebate Amount Claimed	9	56 - 64	9999999V99
Number of Prescriptions	6	65 - 70	999999
Total Reimbursement Amount	10	71 - 80	99999999V99
Correction Flag	1	81 - 81	See Data Element Definitions
Filler *	1	82 - 82	

*   This "filler" character is required only for the record format when states send utilization data to CMS.

NOTE: For the above fields, data elements which are designated as ALPHANUMERIC on the following pages may include numbers, letters, characters, spaces, etc.

MEDICAID DRUG REBATE PROGRAM
STATE INVOICE
(FORM CMS-R-144)
DATA DEFINITIONS

DATA ELEMENT NAME: State Code - Two-character post office abbreviation for state. Alphanumeric, 2 digits.

DATA ELEMENT NAME: Labeler Code - First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager, or distributor of the drug. Numeric values only, 5 digit field, right justified, and 0-filled for 4 digit labeler codes.

DATA ELEMENT NAME: Product Code - Second segment of National Drug Code. Numeric values only, 4 digit field, right justified, 0-filled.

DATA ELEMENT NAME: Package Size Code - Third segment of National Drug Code. Two-digit field, right justified, 0-filled.

DATA ELEMENT NAME: Period Covered - Calendar quarter and year covered by data submission. Numeric, 5 digit field, QYYYY.
Valid Values for Q:
        1 = January 1 - March 31
        2 = April 1 - June 30
        3 = July 1 - September 30
        4 = October 1 - December 31

Valid values for YYYY: Four digit calendar year covered.

MEDICAID DRUG REBATE PROGRAM
STATE INVOICE
(FORM CMS-R-144)
DATA DEFINITIONS

:::

DATA ELEMENT NAME: Product FDA Registration Name (abbreviated) - First 10 characters of product name as it appears on FDA registration form. Alpha-numeric values, 10 digits.

:::

DATA ELEMENT NAME: Rebate Amount Per Unit - The CMS calculated amount per unit type to be claimed as a rebate by the state. Numeric values, 11 digits: 5 whole numbers and 6 decimals.

:::

DATA ELEMENT NAME: Total Units Reimbursed - The total number of unit types of the drug reimbursed by the state during the period covered. Multiply by the per unit rebate amount reported to the state by CMS to get the total rebate amount for this drug for the quarter. Numeric values, 12 digits: 9 whole numbers and 3 decimals.

:::

DATA ELEMENT NAME: Total Rebate Amount Claimed - The total rebate amount the state agency claims it is owed by the labeler for the quarter covered. It is calculated by multiplying the total units reimbursed by the rebate amount per unit. Numeric values, 9 digits: 7 whole numbers and 2 decimal places.

:::

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MEDICAID DRUG REBATE PROGRAM
STATE INVOICE
(FORM CMS-R-144)
DATA DEFINITIONS

:::

DATA ELEMENT NAME: Number of Prescriptions - The number of prescriptions reimbursed for the drug during the quarter. Numeric values, 6 digits, whole numbers only.

:::

DATA ELEMENT NAME: Total Amount Reimbursed by the State - The total amount the state reimbursed to pharmacists for the drug for the quarter covered. Numeric values, 10 digits: 8 whole numbers and 2 decimals.

:::

DATA ELEMENT NAME: Correction Record Flag - Indicates that this record is a correction. Numeric values, 1 digit.

                   Valid Values: 0 = original record
                                      1 = correction record

:::

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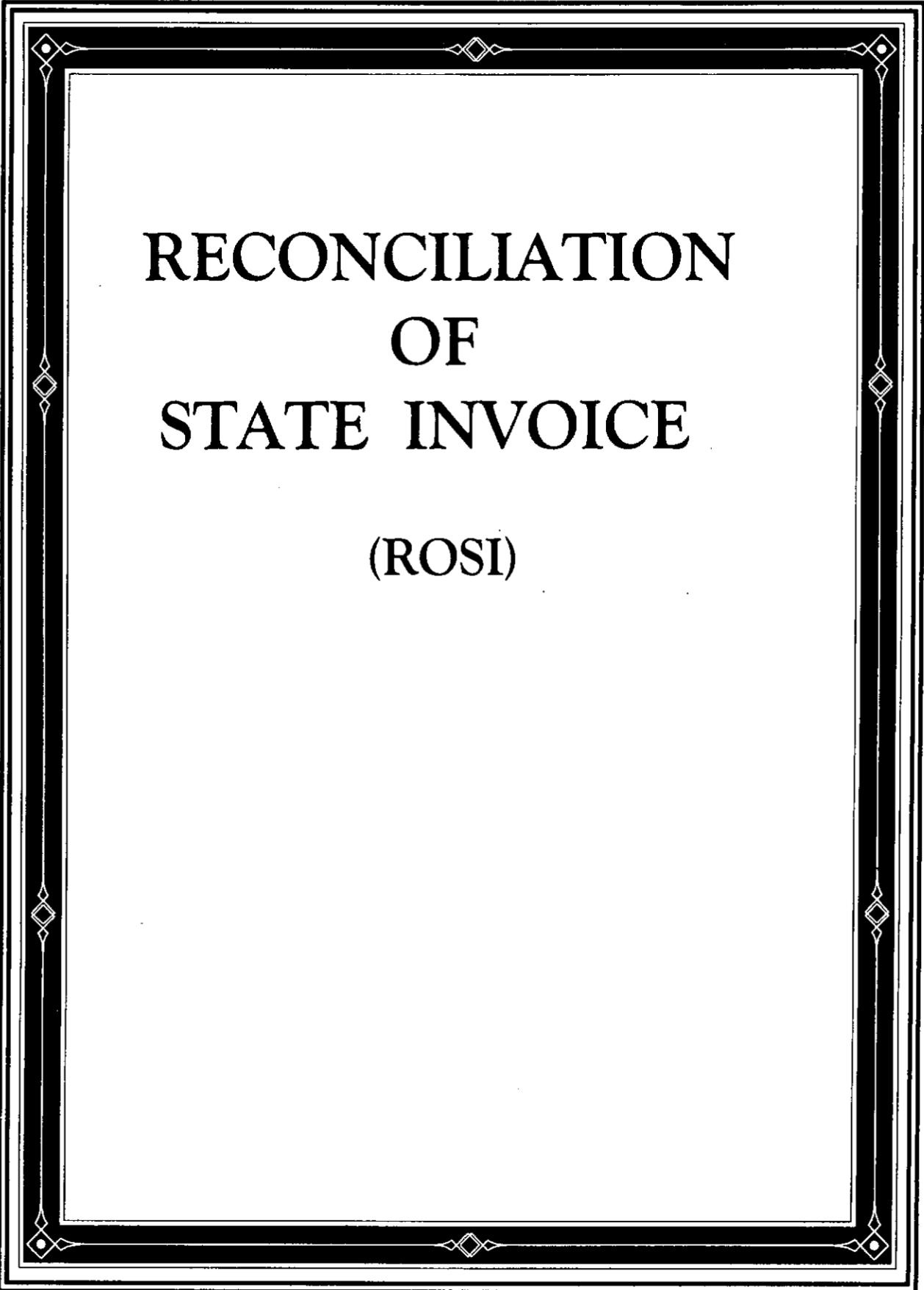
RECONCILIATION
OF
STATE INVOICE

(ROSI)

RECONCILIATION OF STATE INVOICE
(R O S I)

Within 30 days of receipt of the state's invoice for **current quarter** utilization, labelers are required to remit rebate payments, along with the Reconciliation of State Invoice (form CMS-304), better known as the ROSI. The ROSI is to be used only to respond to the state's invoice for current quarter utilization. (Another form, the Prior Quarter Adjustment Statement (PQAS), was developed and is required for response to items outside the current quarter. That form is discussed later in this section of the guide.)

The ROSI form (condensed), including complete instructions (data element definitions, adjustment/dispute code listing, and electronic format), and a sample ROSI (condensed) showing examples of how to complete the form are provided in this section.

REQUIRED USE OF THE ROSI

The OMB has approved CMS's request for the collection of the data on the ROSI as well as the form itself. CMS **requires all labelers** to complete and submit the ROSI (with some exceptions) for each quarterly rebate payment to the state. Instructions for completing the ROSI and the exceptions to its use are contained later in this section.

TRANSMITTING THE ROSI

The labeler may complete and submit the ROSI in one of two media, paper or electronic, depending on the labeler's capabilities. The ROSI instructions include an electronic transmission format. Labelers **MUST submit the ROSI data in the required format regardless of the transmission media selected**.

♣**CLARIFIER**: Portions of this section contain references to URA and RPU. These terms are synonymous in the drug rebate program. URA is mostly used by CMS when referring to the field on the CMS state tape containing the unit rebate amount. RPU is used mainly by states and labelers when referring to the field on the Invoice, ROSI, and PQAS containing the rebate per unit.♣

REVIEWING THE STATE INVOICE

Before remitting a rebate
payment, labelers should
review the invoice for
accuracy.   For example: Is the RPU correct? Are there any unit discrepancies
or inconsistencies, e.g., GM v. ML, units v. scripts? Does the invoice contain
discontinued/terminated or invalid/miscoded NDCs?

When completing the ROSI, labelers may adjust items reported on the state
invoice. Adjusting the RPU and/or the number of units (under limited
circumstances) results in adjustments to the rebate amount claimed on the
invoice.   Labelers adjusting either the RPU or the number of units **MUST**
report a corresponding adjustment code in the space provided. This section
contains a list of adjustment/dispute codes for the ROSI.

Labelers **are not permitted**, except under limited circumstances, to change the
number of units invoiced by the state. The circumstances under which labelers
may adjust the units invoiced are listed below and fully outlined in appendix B
to the ROSI instructions. These circumstances lend themselves to an
immediate resolution of specific invoice discrepancies, as discussed later in
this section.

The limited circumstances under which a labeler may adjust the number of
units reported by the state are:

①   Mutual agreement between state/labeler through
correspondence/telephone contact.

②   Mutual understanding between state/labeler regarding
routine adjustments.

③   Obvious non-routine errors; no response by state to
labeler's correspondence/telephone call attempting
agreement of an adjusted number.

Under no circumstances, other than those listed above, can a labeler adjust the units invoiced by the state. The above circumstances were developed to assist in reducing the number of units disputed.

Once units are adjusted under the above circumstances, if necessary, the remaining units are still subject to dispute. Any adjustments to units after they are officially disputed are made **only by the state** and must be determined using the documentation presented by the labeler and the state under the Dispute Resolution Program. (This program is discussed further in section K of this guide.)

IMMEDIATE RESOLUTION OF INVOICE DISCREPANCIES

Immediate resolution is the agreement of labelers and states to correct obvious data/administrative errors before the rebate payment is due. Invoice items labelers disagree with, may or may not be resolved immediately. Immediate resolution can occur when labelers contact the state to discuss obvious errors that the state would most likely agree need correcting. For example:

1. An RPU that does not reflect any data reported to CMS.
2. Decimal rounding.
3. Unit of measure conversion.

The best way to immediately resolve obvious errors is for labelers to speak directly with the state. If time permits, immediate resolution can be accomplished via written correspondence.

In some cases, labelers have an understanding with states which permits the correction of obvious errors, such as decimal rounding, without discussion.

Immediate resolution can also occur when the error involves the number of units invoiced. For example, an error resulting in an invoice entry of 100,000 units instead of 10,000 units can be resolved with one phone call ☎. This type of resolution eliminates unit disputes.

REBATE PER UNIT

Labelers must remit **accurate** rebate payments, therefore, **the current RPU must be applied to the units being paid**. Regardless of inaccuracies in the state-invoiced RPU, labelers **MUST** use the ROSI to report the correct RPU. The labeler must use the appropriate adjustment code in the space provided on the ROSI when correcting the RPU.

> **✎NOTE:** Labelers must report any pricing data changes to CMS timely. CMS then reports accurate URAs to states which decreases the number of inaccurate, or zero, RPUs on the state's invoice. (Pricing data submission requirements are discussed at the beginning of this section.)

The RPU CMS sends to states is not considered an immediate resolution item because states wait for CMS to send a PPA to "officially" correct RPUs after a labeler submits pricing changes. However, if the labeler discusses other immediate resolution items with the state, they should inform the state that they are correcting an RPU.

ADJUSTMENT/DISPUTE CODES

Labelers must enter the appropriate adjustment/dispute code(s) on the ROSI, as necessary. These codes are listed in Appendix C. They are comprehensive and accommodate any adjustment or dispute. Although codes A-I are generally used as adjustment codes, and codes N-W are generally used for disputes, some codes may be appropriate for either situation. Labelers should only use codes on the list.

The paper and electronic ROSI format accommodates up to three (3) codes each for adjustments and disputes per NDC. Labelers should attach supporting documentation, as needed, to further explain the reason for the adjustment/dispute. However, labelers MUST supply documentation for codes that require it.

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE

COMPANY NAME _____   LABELER CONTACT _____   STATE _____
LABELER CODE _____   PHONE _____   INVOICE NO. _____
QUARTER COVERED _____   FAX _____   DATE _____

PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE PER UNIT	ADJUSTED REBATE PER UNIT	U N I T S				ADJM CODE	DISP CODE	D O L L A R S			
				UNITS INVOICED	ADJUSTED UNITS + or -	LABELER DISPUTED UNITS	UNITS PAID			REBATE AMOUNT INVOICED	INVOICE CORRECTION AMOUNT + or -	WITHHELD INVOICE AMOUNT	REBATE AMOUNT PAID
A	B	C	D	E	F	G	H	I	J	K	L	M	N
TOTALS													

Plus Interest Payment
TOTAL REMITTANCE ═══════

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MEDICAID DRUG REBATE
LABELER INSTRUCTIONS
for
RECONCILIATION OF STATE INVOICE
(FORM CMS-304)

The Medicaid drug rebate Reconciliation of State Invoice (ROSI) is mandated for use by labelers to uniformly explain the adjusted rebate payments to states for the <u>current quarter</u>. The ROSI **MUST** accompany rebate payments made to states **if**:

1. The labeler is NOT paying the full rebate amount due for the current quarter, i.e., the labeler is disputing any units invoiced; or

2. The state invoice contains zeros (0s) in the RPU field due to the labeler's lack of data submittal, **AND** the labeler is remitting the full rebate amount due for the current quarter.

The ROSI is **not required**:

1. **If** the state invoice RPU field contains zeros (0s) but the CMS tape contains an RPU value, **AND** the labeler is remitting the full rebate amount due for the current quarter. Labelers MUST return a copy of the state's invoice with the rebate payment and may optionally pen/ink the RPU field on the invoice copy.

2. **If** the state invoice RPU field contains zeros (0s) due to CMS data edits, **AND** the labeler is remitting the full rebate amount due for the current quarter. Labelers MUST make pen/ink changes to the RPU on a copy of the state's invoice and return it with the full remittance.

3. **If** there are <u>no</u> zero (0) RPU amounts on the state's invoice, **AND** the labeler is remitting the full rebate amount due for the current quarter. Labelers MUST return a copy of the state's invoice with the rebate payment.

⬩NOTE: Labelers may choose to complete and submit the ROSI each quarter regardless of the exceptions listed above.

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The labeler's response (the ROSI or invoice copy) <u>MUST be submitted within 30 days</u> of receiving the state's current quarter invoice.

The labeler may complete and submit the ROSI in one of two media, paper or electronic, depending on the labeler's capabilities. Labelers may develop an automated system for the ROSI using the electronic field size listing attached as Appendix A. Labelers <u>must</u> submit the ROSI in the mandated format regardless of the media selected. No additional information should be entered on the form itself and no information should be omitted unless instructed in the data definitions.

The Labeler Data Definitions, Appendix B, fully explain the information required for each data element on the ROSI. Please refer to these definitions for a complete explanation of the column headings whether completing the ROSI via paper or when developing an electronic medium.

Appendix C, Adjustment and Dispute Codes, lists the codes labelers may enter to explain any adjustments and/or disputes. The codes are comprehensive and accommodate any adjustment or dispute. (This list serves both current and prior quarter reporting (See form CMS-304a).) Codes A-I are generally considered Adjustment Codes, and codes N-W are generally considered Dispute Codes. Only use codes listed in Appendix C.

Labelers may choose up to three codes each for adjustments and disputes per NDC. Attach supporting documentation, as needed, to further explain the reason for the adjustment or dispute. Labelers <u>must</u> supply documentation for codes that require it.

SPECIFIC INSTRUCTIONS

The ROSI is used for response to states' **CURRENT QUARTER UTILIZATION DATA ONLY.** (A separate form CMS-304a, the PQAS, has been developed for labelers to reconcile state utilization changes for prior quarters, prior disputed units, and PPAs.)

1. The ROSI is quarter and invoice specific. Therefore, only current quarter data is reported on this form.

2. Using the data definitions, enter the required information for **each** NDC reported on the state invoice. Each column is "lettered" for ease of reference.

3. Enter grand totals for columns E through H, and K through N. The grand total for column N for all NDCs listed, plus any interest being paid, should equal the remittance to the state.

    However, **IF** a labeler completes and submits a PQAS simultaneously with the ROSI, the amount of the remittance should equal the Total Remittance as shown on the ROSI plus or minus the Total Remittance indicated on the PQAS.

4. Submit the ROSI with the rebate payment to the state.

Examples for Completing the ROSI

Appendix D to these instructions is a condensed ROSI sample showing column entries for four examples. The examples reflect situations such as adjusting the RPU, adjusting the invoiced units, and disputing units.

Disclosure Statement

According to the Paperwork Reduction Act of 1995, no response is required for information collection unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0676. The time required to complete this information collection is estimated to average 63 hours per response, including reviewing instructions, searching existing data sources, gathering the needed data, and completing and reviewing the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

RECORD 1

FIELD	SIZE	REMARKS
Record ID	1	Constant of "1"
Company Name	25	First 25 Positions of Company Name
Labeler Code	5	NDC #1
Quarter Covered	5	QYYYY
Labeler Contact	20	Labeler's Contact Person
Phone	14	Area Code/Phone No./Ext. of Contact
Fax	10	Labeler's Contact Fax Number
State	2	Two Position Postal Abbreviation
Invoice Number	10	Corresponds to State Invoice Number
Date	8	Date Report was Created

RECORD 2

FIELD	SIZE	REMARKS
Record ID	1	Constant of "2"
Labeler Code	5	NDC #1
Product/Package Code	6	NDC #2 and #3
Product Name	10	First 10 Positions of Product Name
Rebate Per Unit	11	99999V999999
Adjusted Rebate Per Unit	11	99999V999999
Units Invoiced	12	999999999V999
Adjusted Units (+/-)	13	9999999999V999
Labeler Disputed Units	12	999999999V999
Units Paid	12	999999999V999
Adjustment Code(s)	3	See HCFA-304, Appendix C
Dispute Code(s)	3	See HCFA-304, Appendix C
Rebate Amount Invoiced	9	9999999V99
Invoice Correction Amount (+/-)	10	99999999V99
Withheld Invoice Amount	9	9999999V99
Rebate Amount Paid	9	9999999V99

MEDICAID DRUG REBATE   **Appendix A**
RECONCILIATION OF STATE INVOICE   **CMS-304**
ELECTRONIC FORMAT

	FIELD	SIZE	REMARKS
RECORD 3	Record ID	1	Constant of "3"
	Labeler Code	5	NDC #1
	Total Units Invoiced	12	999999999V999
	Total Adjusted Units (+/-)	13	9999999999V999
	Total Labeler Disputed Units	12	999999999V999
	Total Units Paid	12	999999999V999
	Total Rebate Amount Invoiced	10	99999999V99
	Total Invoice Correction Amt. (+/-)	11	999999999V99
	Total Withheld Invoice Amount	10	99999999V99
	Total Rebate Amount Paid	10	99999999V99
	Plus Interest Payment	8	999999V99
	Total Remittance	10	99999999V99

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

:::

DATA ELEMENT NAME: Company Name

DATA DEFINITION: Name of company as it appears on the signed rebate agreement.

SPECIFICATIONS: Alpha-numeric values, first 25 positions of company name, left justified, blank filled.

:::

DATA ELEMENT NAME: Labeler Code

DATA DEFINITION: First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.

SPECIFICATIONS: Numeric values only, 5 positions right justified, zero filled; no blanks.

:::

DATA ELEMENT NAME: Quarter Covered

DATA DEFINITION: This data element will always be the **current quarter and year**.

SPECIFICATIONS: Numeric values, 5 position field, QYYYY; no blanks

Valid values for Q:

```
1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31
```

Valid values for YYYY: Four digit calendar year covered.

:::

::

DATA ELEMENT NAME: Labeler Contact

DATA DEFINITION: Labeler's contact person for questions
                     concerning this report.

SPECIFICATIONS: Alpha-numeric values, 20 positions, left
                     justified, first name and last name separated
                     by 1 blank.

::

DATA ELEMENT NAME: Phone

DATA DEFINITION: Telephone number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 14 positions, area code,
                     phone number, and extension, if needed.

::

DATA ELEMENT NAME: Fax

DATA DEFINITION: Fax number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 10 positions, area code
                     and phone number.

::

DATA ELEMENT NAME: State Code

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: Alpha values, 2 position field; no blanks.

::

:::

DATA ELEMENT NAME: Invoice Number

DATA DEFINITION: Invoice identification number. If invoice
                     contains no identification number, this field
                     is left blank.

SPECIFICATIONS: Alpha-numeric values, 10 position field,
                     right justified, blank filled.

:::

DATA ELEMENT NAME: Date

DATA DEFINITION: Date this report was created (not mailed).

SPECIFICATIONS: Numeric values only, 8 position field;
                     no blanks.

:::

DATA ELEMENT NAME: Product/Package Code (Column A)

DATA DEFINITION: Second and Third segments of National Drug
                     Code.

SPECIFICATIONS: Alpha-numeric values, 6 position field, right
                     justified, zero filled; no blanks.

:::

DATA ELEMENT NAME: Product Name (Column B)

DATA DEFINITION: First 10 positions of product name as it
                     appears on the FDA listing form.

SPECIFICATIONS: Alpha-numeric values, 10 positions, left
                     justified; blank filled.

:::

: :

DATA ELEMENT NAME: Rebate Per Unit (Column C)

DATA DEFINITION: CMS-calculated rebate per unit as shown on
                     the state invoice.

SPECIFICATIONS: Numeric values, 11 positions: 5 whole
                     numbers and 6 decimals, right justified.
                     Calculate to five decimals and round to
                     four; pad positions 5 & 6 with zeros. IF
                     NOT AVAILABLE ON THE STATE INVOICE, this
                     field will be zero filled; no blanks.

: :

DATA ELEMENT NAME: Adjusted Rebate Per Unit (Column D)

DATA DEFINITION: Rebate per unit IF different than the
                     amount entered in the Rebate Per Unit
                     field. (The Adjustment Code field must be
                     annotated.)

SPECIFICATIONS: Numeric values, 11 positions: 5 whole
                     numbers and 6 decimals, right justified.
                     Calculate to five decimals and round to
                     four, pad positions 5 & 6 with zeros; blank
                     filled, if not applicable.

: :

DATA ELEMENT NAME: Units Invoiced (Column E)

DATA DEFINITION: This element will always be the state-
                     calculated number of units reimbursed as
                     shown on the invoice.

                     Please note that, upon completion of the
                     ROSI, this element also acts as a
                     compilation of the three elements which
                     follow it (Adjusted Units, Labeler Disputed
                     Units, and Units Paid).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                     numbers and 3 decimals, right justified,
                     zero filled; no blanks.

: :

:::

DATA ELEMENT NAME: Adjusted Units (+ or -)   (Column F)

DATA DEFINITION: The number of units adjusted preceded
by + or -, as a result of one of the
following:

1. The actual Units Invoiced is adjusted
through contact with the state prior
to claims processing. (For example,
if the actual Units Invoiced is
100,000 but the state agrees with the
labeler that the figure should be
10,000 the Adjusted Units will be
-90,000.)

2. The state permits the labeler to make
routine adjustments to actual Units
Invoiced, such as decimal rounding,
or unit of measure conversions. Under
this circumstance, no contact is
necessary prior to claims processing.

3. The labeler adjusts actual Units
Invoiced because an obvious non-
routine error exists and the state
has not responded to the labeler's
contact.

**The Adjustment Code field must be
annotated if Adjusted Units are indicated
for any NDCs.**

SPECIFICATIONS: Numeric values, preceded by a + or - sign,
13 positions: 9 whole numbers and
3 decimals, right justified, blank filled
if not applicable.

:::

::

DATA ELEMENT NAME: Labeler Disputed Units (Column G)

DATA DEFINITION: The number of Invoiced Units being
                     disputed,
                               OR
                     The number of the remaining units being
                     disputed after an adjustment has been
                     made.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                     numbers and 3 decimals, right justified,
                     zero filled; no blanks.

::

DATA ELEMENT NAME: Units Paid (Column H)

DATA DEFINITION: Labeler-calculated number of units paid.
                     This is calculated as follows:

                               Units Invoiced
                     + or -   Adjusted Units
                           -   Labeler Disputed Units

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                     numbers and 3 decimals, right justified,
                     zero filled; no blanks.

::

DATA ELEMENT NAME: Adjustment Code(s)   (Column I)

DATA DEFINITION: Reason(s) labeler has adjusted the rebate
                     per unit or the units invoiced.

SPECIFICATIONS: Alpha values only, 3 positions.
                     Valid values: Refer to Form
                     CMS-304,Appendix C
                     Maximum: 3 Adjustment Codes per NDC

::

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::

DATA ELEMENT NAME: Dispute Code(s)   (Column J)

DATA DEFINITION: Reason(s) labeler is disputing any Units
                   Invoiced.

SPECIFICATIONS: Alpha values only, 3 positions.
                   Valid values: Refer to Form
                   CMS-304,Appendix C
                   Maximum: 3 Dispute Codes per NDC

::

DATA ELEMENT NAME: Rebate Amount Invoiced (Column K)

DATA DEFINITION: State-calculated rebate amount as shown on
                   the invoice.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole
                   numbers and 2 decimals, right justified.
                   If not available, this field will be zero
                   filled; no blanks.

                   Please note that, upon completion of the
                   ROSI, this element also acts as a
                   compilation of the three elements which
                   follow it (Invoice Correction Amount,
                   Withheld Invoice Amount, and Rebate Amount
                   Paid).

::

DATA ELEMENT NAME: Invoice Correction Amount(+or-)(Column L)

DATA DEFINITION: Labeler-corrected invoice amount (+ or -)
                   based on any Adjusted Units and/or the
                   Rebate Per Unit or the Adjusted Rebate Per
                   Unit.

SPECIFICATIONS: Numeric values, preceded by a + or - sign,
                   10 positions: 7 whole numbers and
                   2 decimals, right justified. If not
                   applicable, this field will be zero
                   filled; no blanks, unless the ROSI is
                   manually completed.

::

:::

DATA ELEMENT NAME: Withheld Invoice Amount (Column M)

DATA DEFINITION: Portion of Rebate Amount Invoiced being
                      withheld,
                                   OR,
                      The portion being withheld of the
                      remaining Rebate Amount Invoiced after
                      correction.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole
                      numbers and 2 decimals, right justified.
                      If not applicable, this field will be zero
                      filled; no blanks, unless the ROSI is
                      manually completed.

:::

ATA ELEMENT NAME: Rebate Amount Paid (Column N)

DATA DEFINITION: Per NDC remittance for current quarter.
                      This amount is calculated as follows:

                                   Rebate Amount Invoiced
                      + or -   Invoice Correction Amount
                          -    Withheld Invoice Amount

SPECIFICATIONS: Numeric values, 9 positions: 7 whole
                      numbers and 2 decimals, right justified;
                      zero filled; no blanks.

:::

DATA ELEMENT NAME: Total Units Invoiced

DATA DEFINITION: Total number of units invoiced for all
                      NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                      numbers and 3 decimals, right justified,
                      no blanks.

:::

::

DATA ELEMENT NAME: Total Adjusted Units (+ or -)

DATA DEFINITION: Total number of Adjusted Units for all NDCs
                     (+ or -).

SPECIFICATIONS: Numeric values, preceded by a + or - sign,
                     13 positions, 9 whole numbers and
                     3 decimals, right justified, zero filled;
                     no blanks.

::

DATA ELEMENT NAME: Total Labeler Disputed Units

DATA DEFINITION: Total number of disputed units for all
                     NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                     numbers and 3 decimals, right justified,
                     zero filled; no blanks.

::

DATA ELEMENT NAME: Total Units Paid

DATA DEFINITION: Total number of units paid for all NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                     numbers and 3 decimals, right justified,
                     zero filled; no blanks.

::

DATA ELEMENT NAME: Total Rebate Amount Invoiced

DATA DEFINITION: Total rebate amount invoiced by the state
                     for all NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole
                     numbers and 2 decimals, right justified,
                     zero filled; no blanks.

::

:::

DATA ELEMENT NAME: Total Invoice Correction Amount (+ or -)

DATA DEFINITION: The total Invoice Correction Amount for all
                     NDCs (+ or -).

SPECIFICATIONS: Numeric values, preceded by a + or - sign,
                     11 positions: 8 whole numbers and
                     2 decimals, right justified, zero filled;
                     no blanks.

:::

DATA ELEMENT NAME: Total Withheld Invoice Amount

DATA DEFINITION: Total amount the labeler is withholding for
                     all NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole
                     numbers and 2 decimals, right justified,
                     zero filled; no blanks.

:::

DATA ELEMENT NAME: Total Rebate Amount Paid

DATA DEFINITION: Total rebate amount the labeler is
                     remitting for all NDCs for current quarter.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole
                     numbers and 2 decimals, right justified,
                     zero filled; no blanks.

:::

:.:

DATA ELEMENT NAME: Plus Interest Payment

DATA DEFINITION: Total amount of any <u>interest</u> the labeler is remitting.

SPECIFICATIONS: Numeric values, 8 positions: 6 whole numbers and 2 decimals, right justified, zero filled; <u>no blanks</u>.

:.:

DATA ELEMENT NAME: TOTAL REMITTANCE

DATA DEFINITION: The Total Rebate Amount Paid for <u>all</u> NDCs plus any interest payment.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; <u>no blanks</u>.

:.:

ADJUSTMENT/DISPUTE CODES
for
RECONCILIATION OF STATE INVOICE
and/or
PRIOR QUARTER ADJUSTMENT STATEMENT

A. Rebate per unit amount has been revised by labeler and reported to CMS, as required.

B. Labeler has calculated RPU and/or rebate where none was reported by state.

C. Units invoiced adjusted through mutual agreement between labeler/state. DO NOT USE this code for number of prescriptions or package size discrepancies.

D. Labeler/State unit discrepancy (e.g., GM vs ML).

E. Labeler/state decimal discrepancy.

F. Converted NDC (e.g., package size correction).

G. Transferred NDC to another labeler code (documentation required).

H. Utilization change from the state.

I. Rebate per unit amount adjusted through correspondence between labeler/state. USE THIS CODE ONLY when the state has reported a rebate per unit not based on the CMS tape and adjustment code A is not applicable.
****

N. Discontinued/Terminated NDC for which the shelf life expired more than one year ago.

O. Invalid/miscoded NDC.

P. State units invoiced exceed unit sales. (Attach supporting methodology and data source.)

Q. Utilization/quantity is inconsistent with the number of prescriptions.

R. Utilization/quantity is inconsistent with pharmacy reimbursement levels.

S. Utilization/quantity is inconsistent with state historical trends or current state program information.

T. Utilization/quantity is inconsistent with lowest dispensable package size.

U. Product not rebate eligible. (Give details.)

V. No record of sales directly to state. (Attach data source.)

W. Closed out. All disputes settled.

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE

COMPANY NAME _____ LABELER CONTACT _____ STATE _____
LABELER CODE _____ PHONE _____ INVOICE NO. _____
QUARTER COVERED _(enter current qtr)_ FAX _____ DATE _____

				U	N	I	T	S			D	O	L	L	A	R	S
PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE PER UNIT	ADJUSTED REBATE PER UNIT	UNITS INVOICED	ADJUSTED UNITS + or -	LABELER DISPUTED UNITS	UNITS PAID	ADJM CODE	DISP CODE	REBATE AMOUNT INVOICED	INVOICE CORRECTION AMOUNT + or -	WITHHELD INVOICE AMOUNT	REBATE AMOUNT PAID
A	B	C	D	E	F	G	H	I	J	K	L	M	N
Example A	ABC	00000.100000		000001000.000		000000100.000	000000900.000		P	0000100.00		0000010.00	0000090.00
Example B	DEF	00000.150000		000001000.000	-000000050.000	000000000.000	000000950.000	C		0000150.00	-0000007.50		0000142.50
Example C	GHI	00000.050000	00000.030000	000001000.000		000000200.000	000000800.000	A	P	0000050.00	-0000020.00	0000006.00	0000024.00
Example D	JKL	00000.250000	00000.300000	000001000.000	-000000100.000	000000100.000	000000800.000	AC	Q	0000250.00	+0000020.00	0000030.00	0000240.00
TOTALS				000004000.000	-000000150.000	000000400.000	000003450.000			0000550.00	-0000017.50	0000053.50	0000496.50

Example A The State invoiced for 1000 units with an RPU of 10 cents and a rebate amount claimed of $100. The manufacturer has no adjustments to the RPU or the number of units invoiced, but does dispute 100 units because the units invoiced exceed expected unit sales.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Disputed Units (100), or 900 units. The Withheld Invoice Amount is the Disputed Units (100) times the RPU (.10), or $10. The Rebate Amount Paid is the Rebate Amount Invoiced ($100) less the Withheld Invoice Amount ($10), or $90.

Example B The State invoiced for 1000 units with an RPU of 15 cents and a rebate amount claimed of $150. The manufacturer has no adjustments to the RPU and does not dispute any units, but does adjust the number of units invoiced downward by 50 as agreed upon with the State.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Adjusted Units (50), or 950 units. The Invoice Correction Amount is the Adjusted Units (50) times the RPU (.15), or $7.50. The Rebate Amount Paid is the Rebate Amount Invoiced ($150) less the Invoice Correction Amount ($7.50), or $142.50.

Example C The State invoiced for 1000 units with an RPU of 5 cents and a rebate amount claimed of $50. The manufacturer adjusts the RPU to 3 cents (as reported to CMS but not yet relayed to the State via CMS's quarterly tape), does not adjust the number of units, but does dispute 200 units because the units invoiced exceed expected unit sales.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Disputed Units (-200), or 800 units. The Invoice Correction Amount is the DIFFERENCE between the Rebate Amount Invoiced ($50) and what would have been the Rebate Amount Invoiced based on the Adjusted RPU ($30), or -$20. The Withheld Invoice Amount is the Disputed Units (200) times the Adjusted RPU (.03), or $6. The Rebate Amount Paid is the Rebate Amount Invoiced ($50) less the Invoice Correction Amount (-$20), less the Withheld Invoice Amount ($6), or $24.

Example D The State invoiced for 1000 units with an RPU of 25 cents and a rebate amount claimed of $250. The manufacturer adjusts the RPU to 30 cents (as reported to CMS but not yet relayed to the State via CMS's quarterly tape), adjusts the number of units invoiced downward by 100 as agreed upon with the State, and disputes 100 of the remaining units because utilization is inconsistent with the number of prescriptions.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Adjusted Units (-100) less the Disputed Units (-100), or 800 units. The Invoice Correction Amount is the DIFFERENCE between the Rebate Amount Invoiced ($250) and what would have been the Rebate Amount Invoiced based on the Adjusted RPU and the Adjusted Units ($270), or +$20. The Withheld Invoice Amount is the Disputed Units (100) times the Adjusted RPU (.30), or $30. The Rebate Amount Paid is the Rebate Amount Invoiced ($250) plus the Invoice Correction Amount (-$20), less the Withheld Invoice Amount ($30), or $240.

PRIOR QUARTER ADJUSTMENT STATEMENT

(PQAS)

PRIOR QUARTER ADJUSTMENT STATEMENT
(PQAS)

Labelers are required to reconcile and explain prior quarter actions/payments/credits to states using the PQAS (form CMS-304a). For all prior quarter adjustment activity, labelers must remit any payment due to states, and/or report and show a credit to a rebate previously paid. These transactions **MUST BE REPORTED** to the state using the PQAS.

The PQAS is to be used only:

- to respond to the state's invoice for unit changes for prior quarters;

- to report adjustments to prior disputed units; and

- to report adjustments to prior rebate payments as a result of changes in pricing data, i.e., PPAs.

The PQAS form (condensed), including complete instructions (data element definitions, adjustment/dispute code listing, and electronic format), and a sample PQAS (condensed) showing examples of how to complete the form are provided in this section.

REQUIRED USE OF THE PQAS

The OMB has approved CMS's request for data collection on the PQAS as well as the form itself. CMS **requires all labelers** to complete and submit the PQAS whenever one or more of the items listed above occurs. Instructions for completing the PQAS are contained later in this section.
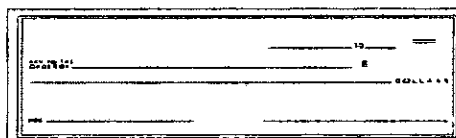
TRANSMITTING THE PQAS

The labeler may submit the PQAS in one of two media, paper or electronic, depending on the labeler's capabilities. The PQAS instructions include an electronic transmission format. Labelers **MUST submit the PQAS data in the required format regardless of the transmission media selected.**

♣ **CLARIFIER**: Portions of this section contain references to URA and RPU. These terms are synonymous in the drug rebate program. URA is mostly used by CMS when referring to the field on the CMS state tape containing the unit rebate amount. RPU is used mainly by states and labelers when referring to the field on the Invoice, ROSI, and PQAS containing the rebate per unit. ♣

REVIEWING THE STATE'S UNIT ADJUSTMENT INVOICE

Before remitting any rebate payment, labelers should review the invoice for accuracy. For example: Is the RPU correct? Are there any unit discrepancies?

When completing the PQAS, labelers may adjust items reported on the state invoice. Adjusting the RPU and/or the number of adjusted units (under limited circumstances) results in adjustments to the rebate amount claimed on the invoice. Labelers adjusting either the RPU or the number of units **MUST** report a corresponding adjustment code in the space provided. This section contains a list of adjustment/dispute codes for the PQAS.

Labelers **are not permitted**, except under limited circumstances, to change the number of units invoiced by the state. The circumstances under which labelers may adjust the units invoiced are listed below and fully outlined in appendix B to the PQAS instructions. These circumstances lend themselves to an immediate resolution of specific invoice discrepancies, as discussed later in this section.

The limited circumstances under which a labeler may adjust the number of units reported by the state are:

①   Mutual agreement between state/labeler through correspondence/telephone contact.

②   Mutual understanding between state/labeler regarding routine adjustments.

③   Obvious non-routine errors; no response by state to labeler's correspondence/telephone call attempting agreement of an adjusted number.

Under no circumstances, other than those listed above, can a labeler adjust the units invoiced by the state. The above circumstances were developed to assist in reducing the number of units disputed.

Once units are adjusted under the above circumstances, if necessary, the remaining units are still subject to dispute. Any adjustments to units after they are officially disputed are made **only by the state** and must be determined using the documentation presented by the labeler and the state under the Dispute Resolution Program. (This program is discussed further in section K of this guide.)

IMMEDIATE RESOLUTION OF INVOICE DISCREPANCIES

Immediate resolution is the agreement of labelers and states to correct obvious administrative/data errors before rebate payment is due. Unit adjustment invoice items labelers disagree with may or may not be resolved immediately. Immediate resolution can occur when labelers contact the state to discuss obvious errors that the state would most likely agree need correcting. For example:

1. An RPU that does not reflect any data reported to CMS.
2. Decimal rounding.
3. Unit of measure conversion.

The best way to immediately resolve obvious errors is for labelers to speak directly with the state. If time permits, immediate resolution can be accomplished via written correspondence.

In some cases, labelers have an understanding with states which permits the correction of obvious errors, such as decimal rounding, without discussion.

Immediate resolution can also occur when the error involves the number of adjusted units invoiced. For example, an error resulting in an invoice entry of 10,000 units instead of 1,000 units can be resolved with one phone call ☎. This type of resolution eliminates unit disputes.

REBATE PER UNIT

Labelers must remit accurate rebate payments, therefore, **the current RPU must be applied to units being paid.** For example, if the state submits a unit adjustment invoice, but the RPU reported is inaccurate, labelers MUST use the PQAS to report the correct RPU. The correct RPU must be applied to all prior quarter adjustment activity, i.e., state unit adjustments, prior disputed unit adjustments, or PPA processing. Whenever the RPU is corrected on the PQAS, the appropriate adjustment code **must be** annotated in the space provided.

> ✎**NOTE:**   Labelers must report any pricing data changes to CMS timely. CMS then reports accurate URAs to states which decreases the number of inaccurate RPUs on the state's invoice. (Pricing data submission requirements are discussed at the beginning of this section.)

ADJUSTMENT/DISPUTE CODES

Labelers must enter the appropriate adjustment/dispute code(s) on the PQAS. These codes are listed in Appendix C. They are comprehensive and accommodate any adjustment or dispute. Although codes A-I are generally used as adjustment codes, and codes N-W are generally used for disputes, some codes may be appropriate for either situation. Labelers should only use codes on the list.

The paper or electronic PQAS format accommodates up to three (3) codes each for adjustments and disputes per NDC. Labelers should attach supporting documentation, as needed, to further explain the reason for the adjustment/dispute. However, labelers MUST supply documentation for codes that require it.

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(for reconciling unit changes, disputed units, and PPAs)

COMPANY NAME _____
LABELER CODE _____
QUARTER COVERED _____

LABELER CONTACT _____
PHONE _____
FAX _____

STATE _____
INVOICE NO. _____
DATE _____

PRODUCT PACKAGE CODE	PRODUCT NAME	ORIGINAL REBATE PER UNIT	CURRENT REBATE PER UNIT	ORIGINAL UNITS INVOICED (U)	CURRENT UNITS TO DATE (N)	PRIOR UNITS PAID (I)	CURRENT UNITS PAID TO DATE (T)	PRIOR UNITS DISPUTED (S)	CURRENT UNITS DISPUTED TO DATE (D)	ORIGINAL AMOUNT INVOICED (O)	REVISED INVOICE AMOUNT (L)	PRIOR AMOUNT PAID (L)	CURRENT AMT PAID TO DATE (A)	AMT PAID THIS TRANS (R S)	ADJM CODE	DISP CODE
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
TOTALS																

Plus Interest Payment
Total Remittance _____

MEDICAID DRUG REBATE
LABELER INSTRUCTIONS
for
PRIOR QUARTER ADJUSTMENT STATEMENT
(FORM CMS-304a)

The Medicaid drug rebate PQAS is mandated for use by labelers to uniformly explain prior quarter actions/payments/credits to states. This form may accompany the ROSI or may be submitted separately. In either case, the PQAS must accompany rebate payments or payment adjustments for a prior quarter.

The labeler may complete and submit the PQAS in one of two media, paper or electronic, depending on the labeler's capabilities. Labelers may develop an automated system for the PQAS using the electronic field size listing attached as Appendix A. Labelers MUST submit the PQAS in the mandated format regardless of the media selected. No additional information should be entered on the form itself and no information should be omitted unless instructed in the data definitions.

The Labeler Data Definitions, Appendix B, fully explain the information required for each data element on the PQAS. Please refer to these definitions for a complete explanation of the column headings whether completing the PQAS via paper or when developing an electronic medium.

Appendix C, Adjustment and Dispute Codes, lists the codes you may enter to explain any adjustments and/or disputes. The codes are comprehensive and accommodate any adjustment or dispute. (This list serves both prior and current quarter reporting (see form CMS-304).) Codes A-I are generally considered Adjustment Codes; and codes N-W are generally considered Dispute Codes. Only use codes listed in Appendix C.

Labelers may choose up to three codes each for adjustments and disputes per NDC. Attach supporting documentation, as needed, to further explain the reason for the adjustment or dispute. Labelers must supply documentation for codes that require it.

SPECIFIC INSTRUCTIONS

The PQAS is used for reporting all <u>PRIOR QUARTER</u> actions, i.e., invoiced unit changes, prior disputed unit adjustments, and PPAs.

1. The PQAS is <u>quarter specific</u>. The labeler must complete a separate PQAS for <u>each</u> prior quarter reconciled.

2. Using the data definitions, enter the required information for <u>each</u> NDC reported to the state. Each column is "lettered" for ease of reference.

3. Enter grand totals for columns E through O. The grand total for column O for all NDCs listed, plus interest being paid, should equal the remittance to the state.

    ❖NOTE: If the labeler completes and submits the PQAS with the ROSI, the amount of the remittance should equal the Total Remittance shown on the ROSI, plus or minus the Total Remittance on the PQAS.

4. A brief explanation of any interest payment <u>must</u> be provided.

5. Submit the completed PQAS with the payment/credit for all prior quarters.

Examples for Completing the PQAS

Appendix D to these instructions is a condensed PQAS sample showing column entries for five examples. The examples reflect situations such as invoiced unit changes, prior disputed unit adjustments, and PPAs.

Disclosure Statement

According to the Paperwork Reduction Act of 1995, no response is required for information collection unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0676. The time required to complete this information collection is estimated to average 63 hours per response, including reviewing instructions, searching existing data sources, gathering needed data, and completing and reviewing the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

RECORD 1

FIELD	SIZE	REMARKS
Record ID	1	Constant of "1"
Company Name	25	First 25 Positions of Company Name
Labeler Code	5	NDC #1
Quarter Covered	5	QYYYY
Labeler Contact	20	Labeler's Contact Person
Phone	14	Area Code/Phone No./Ext. of Contact
Fax	10	Labeler's Contact Fax Number
State	2	Two Position Postal Abbreviation
Invoice Number	10	Corresponds to State Invoice Number
Date	8	Date Report was Created

RECORD 2

FIELD	SIZE	REMARKS
Record ID	1	Constant of "2"
Labeler Code	5	NDC #1
Product/Package Code	6	NDC #2 and #3
Product Name	10	First 10 Positions of Product Name
Original Rebate Per Unit	11	99999V999999
Current Rebate Per Unit	11	99999V999999
Original Units Invoiced	12	999999999V999
Current Units to Date	12	999999999V999
Prior Units Paid	12	999999999V999
Current Units Paid to Date	12	999999999V999
Prior Units Disputed	12	999999999V999
Current Units Disputed to Date	12	999999999V999
Original Amount Invoiced	9	9999999V99
Revised Invoice Amount	9	9999999V99
Prior Amount Paid	9	9999999V99
Current Amount Paid to Date	9	9999999V99
Amount Paid This Transaction	9	9999999V99
Adjustment Code(s)	3	See HCFA-304a, Appendix C
Dispute Code(s)	3	See HCFA-304a, Appendix C

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
ELECTRONIC FORMAT

	FIELD	SIZE	REMARKS
RECORD 3	Record ID	1	Constant of "3"
	Labeler Code	5	NDC #1
	Total Original Units Invoiced	12	Total for all NDCs 999999999V999
	Total Current Units to Date	12	Total for all NDCs 999999999V999
	Total Prior Units Paid	12	Total for all NDCs 999999999V999
	Total Current Units Paid to Date	12	Total for all NDCs 999999999V999
	Total Prior Units Disputed	12	Total for all NDCs 999999999V999
	Total Current Units Disputed to Date	12	Total for all NDCs 999999999V999
	Total Original Amount Invoiced	10	Total for all NDCs 99999999V99
	Total Revised Invoice Amount	10	Total for all NDCs 99999999V99
	Total Prior Amount Paid	10	Total for all NDCs 99999999V99
	Total Current Amount Paid to Date	10	Total for all NDCs 99999999V99
	Total Amount Paid This Transaction	10	Total for all NDCs 99999999V99
	Plus Interest Payment	8	Total for all NDCs 999999V99
	Total Remittance	10	Total for all NDCs 99999999V99

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form CMS-304a)
LABELER DATA DEFINITIONS

:::

DATA ELEMENT NAME: Company Name

DATA DEFINITION: Name of company as it appears on the signed rebate agreement.

SPECIFICATIONS: Alpha-numeric values, first 25 positions of company name, left justified, blank filled.

:::

DATA ELEMENT NAME: Labeler Code

DATA DEFINITION: First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.

SPECIFICATIONS: Numeric values only, 5 positions right justified, zero filled; no blanks.

:::

DATA ELEMENT NAME: Quarter Covered

DATA DEFINITION: This data element will always be a **prior** quarter and year.

SPECIFICATIONS: Numeric values, 5 position field, QYYYY; no blanks

Valid values for Q:

        1 = January 1 - March 31
        2 = April 1 - June 30
        3 = July 1 - September 30
        4 = October 1 - December 31

Valid values for YYYY: Four digit calendar year covered.

:::

:::

DATA ELEMENT NAME: Labeler Contact

DATA DEFINITION: Labeler's contact person for questions
                      concerning this report.

SPECIFICATIONS: Alpha-numeric values, 20 positions, left
                      justified, first name and last name separated
                      by 1 blank.

:::

DATA ELEMENT NAME: Phone

DATA DEFINITION: Telephone number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 14 positions, area
                      code, phone number, and extension, if needed.

:::

DATA ELEMENT NAME: Fax

DATA DEFINITION: Fax number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 10 positions, area code
                      and phone number.

:::

DATA ELEMENT NAME: State

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: Alpha values, 2 position field; no blanks

:::

::

DATA ELEMENT NAME: Invoice Number

DATA DEFINITION: Invoice identification number. Use the
                     invoice number for state unit changes
                     currently submitted, or the most recent
                     invoice number for the quarter you are
                     initiating PPAs or adjusting prior disputed
                     units. If invoice contains no identification
                     number, this field is left blank.

SPECIFICATIONS: Alpha-numeric values, 10 position field,
                     right justified, blank filled.

::

DATA ELEMENT NAME: Date

DATA DEFINITION: Date this report was created (not mailed).

SPECIFICATIONS: Numeric values only, 8 position field;
                     no blanks.

::

DATA ELEMENT NAME: Product/Package Code (Column A)

DATA DEFINITION: Second and Third segments of National Drug
                     Code.

SPECIFICATIONS: Alpha-numeric values, 6 position field, right
                     justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Product Name (Column B)

DATA DEFINITION: First 10 positions of product name as it
                     appears on the FDA listing form.

SPECIFICATIONS: Alpha-numeric values, 10 positions, left
                     justified; blank filled.

::

::

DATA ELEMENT NAME: Original Rebate Per Unit (Column C)

DATA DEFINITION: The rebate per unit reported on the original
                     invoice for the quarter involved. This will
                     never change, even if it is "zero."

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers
                     and 6 decimals, right justified. Calculate
                     to five decimals and round to four, pad
                     positions 5 & 6 with zeros. IF NOT AVAILABLE
                     ON THE STATE INVOICE, this field is zero
                     filled; no blanks.

::

DATA ELEMENT NAME: Current Rebate Per Unit (Column D)

DATA DEFINITION: The most recent calculated rebate per unit.
                     (The Adjustment Code field must be annotated
                     if this number is different from the Original
                     Rebate Per Unit.)

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers
                     and 6 decimals, right justified. Calculate
                     to five decimals and round to four, pad
                     positions 5 & 6 with zeros; blank filled, if
                     not applicable.

::

DATA ELEMENT NAME: Original Units Invoiced (Column E)

DATA DEFINITION: This element will always be the number of
                     units first reported for the quarter
                     involved. This number never changes.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                     and 3 decimals, right justified, no blanks.

::

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:::

DATA ELEMENT NAME: Current Units To Date   (Column F)

DATA DEFINITION: The most recent number of units reported by
                      the state or agreed upon under one of the
                      circumstances below. This number can be
                      more, less, or the same as the original, and
                      can change from time to time, but always
                      enter the most recent.

                      Unit adjustments agreed upon subsequent to
                      state invoicing may be the result of the
                      following:

                      1.   Contact with the state.

                      2.   The labeler and the state regard the
                            adjustments as routine. For example,
                            decimal rounding or unit of measure
                            conversions. Under this circumstance, no
                            contact is necessary.

                      3.   An obvious non-routine error exists and
                            the state has not responded to the
                            labeler's contact attempts.

                      **The Adjustment Code field is annotated if the
                      units entered are different from the Original
                      Units Invoiced (Column E) or those currently
                      invoiced for the quarter involved.**

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                      and 3 decimals, right justified, no blanks.

:::

:::

DATA ELEMENT NAME: Prior Units Paid (Column G)

DATA DEFINITION: The total units paid for this NDC up to, but not including, the date of this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

:::

DATA ELEMENT NAME: Current Units Paid To Date (Column H)

DATA DEFINITION: The total units paid for this NDC, including those paid with this report. This can be more, less, or the same as the Prior Units Paid (Column G).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

:::

DATA ELEMENT NAME: Prior Units Disputed (Column I)

DATA DEFINITION: The total units disputed for this NDC up to, but not including, the date of this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

:::

DATA ELEMENT NAME: Current Units Disputed To Date (Column J)

DATA DEFINITION: The total units disputed for this NDC, including those disputed with this report. This can be more, less, or the same as the Prior Units Disputed (Column I).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

:::

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:::

DATA ELEMENT NAME: Original Amount Invoiced (Column K)

DATA DEFINITION: The number of ORIGINAL UNITS INVOICED
(Column E) times the ORIGINAL REBATE PER UNIT
(Column C). This number never changes, even
if it is "zero."

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
and 2 decimals, right justified, zero filled,
no blanks.

:::

DATA ELEMENT NAME: Revised Invoice Amount (Column L)

DATA DEFINITION: The number of Current Units To Date
(Column F) times the Current Rebate Per Unit
(Column D). This can be more, less, or the
same as the Original Amount Invoiced
(Column K).

PECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
and 2 decimals, right justified, zero filled,
no blanks.

:::

DATA ELEMENT NAME: Prior Amount Paid (Column M)

DATA DEFINITION: The amount paid for this NDC up to, but not
including, the date of this report.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
and 2 decimals, right justified, zero filled,
no blanks.

:::

:::

DATA ELEMENT NAME: Current Amount Paid To Date (Column N)

DATA DEFINITION: The amount paid to date for this NDC,
                     including any amount paid with this report.
                     This can be more, less, or the same as the
                     Prior Amount Paid (Column M), and is the sum
                     of Current Units Paid To Date (Column H)
                     times the Current Rebate Per Unit (Column D).

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

:::

DATA ELEMENT NAME: Amount Paid This Transaction (Column O)

DATA DEFINITION: The amount from Column N less the amount from
                     Column M (Current Amount Paid To Date minus
                     Prior Amount Paid). This amount can be a
                     positive or negative number.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

:::

DATA ELEMENT NAME: Adjustment Code(s) (Column P)

DATA DEFINITION: Reason(s) labeler has:

                     1.   Entered a Current Rebate Per Unit that
                          differs from the Original Rebate Per
                          Unit,
                                         AND/OR

                     2.   Has entered a Current Units To Date
                          number that differs from the number of
                          units currently invoiced for the quarter
                          involved.

SPECIFICATIONS: Alpha values only, 3 positions.
                     Valid values: Refer to CMS-304a, Appendix C
                     Maximum: 3 Adjustment Codes per NDC

:::

::

DATA ELEMENT NAME: Dispute Code(s) (Column Q)

DATA DEFINITION: Reason(s) labeler is:

1. Disputing any original units or current units invoiced for the quarter involved,

AND/OR

2. Disputing the difference, or any part thereof, of the remaining units after adjustment.

SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to CMS-304a, Appendix C
Maximum: 3 Dispute Codes per NDC

::

DATA ELEMENT NAME: Total Original Units Invoiced

DATA DEFINITION: Total units in Column E for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, no blanks.

::

DATA ELEMENT NAME: Total Current Units To Date

DATA DEFINITION: Total units in Column F for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions, 9 whole numbers and 3 decimals, right justified, no blanks.

::

DATA ELEMENT NAME: Total Prior Units Paid

DATA DEFINITION: Total units in Column G for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled, no blanks.

::

: :

DATA ELEMENT NAME: Total Current Units Paid To Date

DATA DEFINITION: Total units in Column H for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                     numbers and 3 decimals, right justified, zero
                     filled; no blanks.

: :

DATA ELEMENT NAME: Total Prior Units Disputed

DATA DEFINITION: Total units in Column I for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                     and 3 decimals, right justified, zero filled,
                     no blanks.

: :

DATA ELEMENT NAME: Total Current Units Disputed To Date

DATA DEFINITION: Total units in Column J for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                     and 3 decimals, right justified, zero filled,
                     no blanks.

: :

DATA ELEMENT NAME: Total Original Amount Invoiced

DATA DEFINITION: Total amount in Column K for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

: :

:::

DATA ELEMENT NAME: Total Revised Invoice Amount

DATA DEFINITION: Total amount in Column L for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

:::

DATA ELEMENT NAME: Total Prior Amount Paid

DATA DEFINITION: Total amount in Column M for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

:::

DATA ELEMENT NAME: Total Current Amount Paid To Date

DATA DEFINITION: Total amount in Column N for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

:::

DATA ELEMENT NAME: Total Amount Paid This Transaction

DATA DEFINITION: Total amount in Column O for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

:::

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::

DATA ELEMENT NAME: Plus Interest Payment

DATA DEFINITION: Total amount of interest the labeler is
                     remitting.

SPECIFICATIONS: Numeric values, 8 positions: 6 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

::

DATA ELEMENT NAME: Total Remittance

DATA DEFINITION: The Total Amount Paid This Transaction for
                     all NDCs plus any interest payment.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

::

**ADJUSTMENT/DISPUTE CODES
for
RECONCILIATION OF STATE INVOICE
and/or
PRIOR QUARTER ADJUSTMENT STATEMENT**

A. Rebate per unit amount has been revised by labeler and reported to CMS, as required.

B. Labeler has calculated RPU and/or rebate where none was reported by state.

C. Units invoiced adjusted through mutual agreement between labeler/state. DO NOT USE this code for number of prescriptions or package size discrepancies.

D. Labeler/State unit discrepancy (e.g., GM vs ML).

E. Labeler/state decimal discrepancy.

F. Converted NDC (e.g., package size correction).

G. Transferred NDC to another labeler code (documentation required).

H. Utilization change from the state.

I. Rebate per unit amount adjusted through correspondence between labeler/state. USE THIS CODE ONLY when the state has reported a rebate per unit not based on the CMS tape and adjustment code A is not applicable.
****

N. Discontinued/Terminated NDC for which the shelf life expired more than one year ago.

O. Invalid/miscoded NDC.

P. State units invoiced exceed unit sales. (Attach supporting methodology and data source.)

Q. Utilization/quantity is inconsistent with the number of prescriptions.

R. Utilization/quantity is inconsistent with pharmacy reimbursement levels.

S. Utilization/quantity is inconsistent with state historical trends or current state program information.

T. Utilization/quantity is inconsistent with lowest dispensable package size.

U. Product not rebate eligible. (Give details.)

V. No record of sales directly to state. (Attach data source.)

W. Closed out. All disputes settled.

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MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(for reconciling unit changes, disputed units, and PPAs)

COMPANY NAME _____ LABELER CONTACT _____ STATE _____
LABELER CODE _____ PHONE _____ INVOICE NO. _____
QUARTER COVERED _____ FAX _____ DATE _____

PRODUCT PACKAGE CODE	PRODUCT NAME	ORIGINAL REBATE PER UNIT	CURRENT REBATE PER UNIT	ORIGINAL UNITS INVOICED	CURRENT UNITS TO DATE	PRIOR UNITS PAID	CURRENT UNITS PAID TO DATE	PRIOR UNITS DISPUTED	CURRENT UNITS DISPUTED TO DATE	ORIGINAL AMOUNT INVOICED	REVISED INVOICE AMOUNT	PRIOR AMOUNT PAID	CURRENT AMT PAID TO DATE	AMT PAID THIS TRANS	ADJM CODE	DISP CODE
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Example 1		0.260000	0.160000	700	500	700	500	0	0	182.00	80.00	182.00	80.00	-102.00	AH	
Example 2		0.250000	0.250000	1000	1240	1000	1190	0	50	250.00	310.00	250.00	297.50	47.50	CH	T
Example 3		0.130000	0.030000	1000	900	700	750	300	150	130.00	27.00	91.00	22.50	-68.50	AH	Q
Example 4		0.120000	0.020000	500	500	425	395	75	105	60.00	10.00	51.00	7.90	-43.10	A	P
Example 5		0.300000	0.300000	700	500	425	500	275	0	210.00	150.00	127.50	150.00	22.50	H	W
TOTALS				3900	3640	3250	2335	650	305	832.00	577.00	701.50	557.90	-143.60		

Example 1 — State submits a unit change of -200. The original units invoiced were 700 with none disputed. The original RPU of 26 cents has changed to 16 cents.

Column Entries — The Revised Invoice Amount is the number of Current Units (500) times the Current RPU (.16), or $80.
The Prior Amount Paid is the Prior Units Paid (700) times the Original RPU (.26), or $182. The Current Amount Paid To Date is the Current Units Paid To Date (500) times the Current RPU (.16), or $80. The Amount Paid This Transaction is the Current Amount Paid To Date ($80) minus the Prior Amount Paid ($182), or -$102.

Example 2 — State submits a unit change of +300. The labeler adjusts those units downward by 60 as agreed upon with the State, and disputes 50 of the remaining 240 units because quantity is inconsistent with the lowest dispensable package size. The original units invoiced were 1000 with none disputed. The RPU of 25 cents has never changed.

Column Entries — Current Units To Date is the Original Units Invoiced (1000) plus the unit change of 300 minus the 60 units adjusted, or 1240.
Current Units Paid To Date is the Current Units To Date (1240) minus the Current Units Disputed (50), or 1190.
The Revised Invoice Amount is the Current Units To Date (1240) times the Current RPU (.25), or $310. The Prior Amount Paid is the Prior Units Paid (1000) times the Original RPU (.25), or $250. The Current Amount Paid To Date is the Current Units Paid To Date (1190) times the Current RPU (.25), or $297.50. The Amount Paid This Transaction is the Current Amount Paid To Date ($297.50) minus the Prior Amount Paid ($250), or $47.50.

Example 3 — State submits a unit change of -100. The labeler now pays 50 of the prior disputed units. The original units invoiced were 1000 with 300 previously disputed because utilization is inconsistent with the number of prescriptions. The original RPU of 13 cents has changed to 3 cents.

Column Entries — Prior Units Paid is the Original Units Invoiced (1000) minus the Prior Units Disputed (300), or 700. The Current Units Paid To Date is the Prior Units Paid (700) plus 50 of the previously disputed units now being paid, or 750. The Current Units Disputed To Date is the Prior Units Disputed (300) minus the unit change of 100 minus the 50 units previously disputed but now paid, or 150. The Revised Invoice Amount is the Current Units To Date (900) times the Current RPU (.03), or $27. The Prior Amount Paid is the Prior Units Paid (700) times the Original RPU (.13), or $91. The Current Amount Paid To Date is the Current Units Paid To Date (750) times the Current RPU (.03), or $22.50. The Amount Paid This Transaction is the Current Amount Paid To Date ($22.50) minus the Prior Amount Paid ($91), or -$68.50.

Example 4 — The RPU of 12 cents has changed to 2 cents. The labeler previously disputed 75 units and now is disputing an additional 30 because units exceed expected sales. The original units invoiced were 500.

Column Entries — The Current Units To Date is 500 because there is no utilization change reported. The Prior Units Paid is the Original Units Invoiced (500) minus the Prior Units Disputed (75), or 425. The Current Units Paid To Date is the Current Units To Date (500) minus the Current Units Disputed To Date (105), or 395. The Current Units Disputed To Date is the Prior Units Disputed (75) plus the additional 30 units now being disputed, or 105. The Revised Invoice Amount is the Current Units To Date (500) times the Current RPU (.02), or $10. The prior Amount Paid is the Prior Units Paid (425) times the original RPU (.12), or $51. The Current Amount Paid To Date is the Current Units Paid To Date (395) times the Current RPU (.02), or $7.90. The Amount Paid This Transaction is the Current Amount Paid To Date ($7.90) minus the Prior Amount Paid ($51), or -$43.10.

Example 5 — The State submits a unit change of -200. The labeler now pays all remaining disputed units. The original units invoiced were 700 with 275 previously disputed. The RPU of 30 cents has never changed.

Column Entries — Because the labeler is paying all remaining disputes, the Current Units Paid To Date is the Same as the Current Units To Date. The Current Units Disputed To Date is zero because the Prior Units Disputed is reduced by the unit change of -200 and further reduced by payment of the 75 previsouly disputed units. The Revised Invoice Amount is the Current Units To Date (500) times the Current RPU (.30), or $150. The Prior Amount Paid is the Prior Units Paid (425) times the Original RPU (.30), or $127.50. The Current Amount Paid To Date is the Current Units Paid To Date (500) time the Current RPU (.30), or $150. The Amount Paid This Transaction is the Current Amount Paid To Date ($150) minus the Prior Amount Paid ($127.50), or $22.50.

CMS
DATA
RESPONSIBILITIES

DATA PRE-EDITS

As CMS receives quarterly pricing data, it goes through various "pre-edit" edits, depending on the transmission medium used.

☞ **For paper transmission**, data is reviewed prior to data entry to:

1. Make sure that all labeler NDCs have prices included.

2. Make sure prices look correct and are consistent with Unit Type and prior data submissions.

   For example: If a product is an "I" drug, BP must be included with AMP and must be equal to or less than AMP. AMP/BP are checked against Unit Type. If Unit Type is "EA" and AMP equals .02, it would appear that there is a problem. Conversely, if Unit Type is "ML" and AMP equals 125.38, the price would be questioned.

3. Assure that multiple package sizes of a product contain the same prices.

4. Determine whether Baseline data changes are appropriate before they are accepted.

☞ **When diskettes are received:**

1. They are logged and checked for any computer virus. Any diskettes containing a virus are cleaned to remove the virus, uploaded to the mainframe, and run through the same edit program as the Sterling Commerce electronic transmissions. (See below)

2. A phone call ☏ is made to inform the labeler's technical contact about the virus. CMS informs the technical contact that if the labeler's next quarter's diskette contains a virus, termination ☹ from the program may be forthcoming.

G2
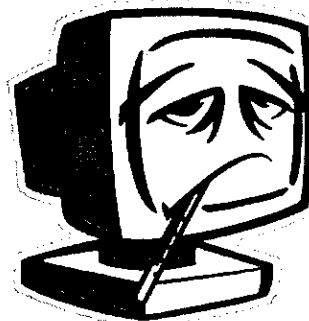
☞ **Sterling Commerce transmitters** send their data to a designated electronic mailbox. The data in the mailbox:

1. Is polled by the CMS Data Center at intervals during the quarter. The mailbox is polled several times a day the month after a quarter. During months 2 and 3, it is generally polled twice a day.

2. Is uploaded and run through an edit program which kicks out records that are incorrectly coded or that have no match on CMS's MDRI master file.

DATA EDIT REPORTS
(Before and After the URA Calculations)

B E F O R E...

When necessary, edit reports are sent to labelers with an introductory letter explaining what to look for and what to do with data causing "alert" messages, as well as data that actually "rejects." Labelers are asked to make corrections and resubmit the data using the same transmission medium used for the original data submission.

The edit report shows messages for both rejected and alerted records. Records that reject will do so for a number of reasons. If a quarterly pricing record rejects, it would be due to:

♦ AMP/BP not numeric
♦ AMP/BP missing
♦ Product record not on MDRI (NDC does not exist on CMS's file)
♦ Different package sizes (NDC 3) of a product (NDC 2) with different AMP or BP values.

If a Baseline record rejects, it would be for:

♦ Field not within specific range (e.g., DESI not between 2 & 6, Unit Type not valid)
♦ Numeric field not numeric
♦ Market Date/ FDA Approval Date missing (see explanation below)
♦ Baseline AMP missing for Market Date < 10-01-93
♦ Baseline change (Correction Flag = "1") with no match on MDRI
♦ Baseline addition (Correction Flag = "0"), NDC already exists on MDRI
♦ Baseline Field(s) (Unit Type, Drug Category, Drug Type, DESI, Therapeutic Equivalent, Market Date, FDA Approval Date) on one package size (NDC 3) not equal to field on established product (NDC 2)

<u>Market Date/FDA Approval Date reject, additional explanation</u> - **Prior to** the enactment of OBRA '93, Baseline records entered on the MDRI system with blank Market and/or FDA Approval Dates would be accepted and assumed to have been introduced prior to 10-01-90. NDCs introduced after this date were required to have Market Dates only. **OBRA '93 requires** that BOTH Dates be present, Market Date to assure proper Baseline CPI-U for the "creep" calculation, and FDA Approval Date to assure that a drug follows its NDA/ANDA date, **NOT** its new NDC number.

If labelers attempt to change a Baseline record that originally had blank dates without updating them as part of any change record, the record will reject with the message: **Market/FDA Approval Date(s) missing.** This data must be supplied before any changes are allowed. If this happens to be an old NDC that came on the market prior to the start of the drug rebate program, and labelers can not track down one or both of these dates, the "magical" 09-30-90 date can be entered. This will assure that the CPI-U creep calculation will be performed using OBRA '90 rules, rather than OBRA '93 rules.

Besides data rejects, several "**Alert**" messages may occur on a labeler's edit report. These messages are listed below and explained in detail below.

- ▲ BP greater than AMP
- ▲ DESI change attempted

▲ BP greater than AMP

In general, the definition of BP is that it is the lowest price at which a labeler sold its drug for the quarter. Therefore, BP can not be higher than other prices paid. AMP can occasionally be calculated as actually lower than Best Price. (See section F for more information.) In this instance, labelers make the BP **EQUAL TO AMP** (i.e., lower the BP) for the quarter. Again, **this record is NOT rejected**; however, labelers should make a correction prior to or with their next quarter's pricing data submission.

▲ DESI change attempted

CMS breaks both DESI and non-DESI drugs into specific categories. The values of "2", "3", and "4" are used for (non-DESI) drugs that will be covered by the program; values of "5" and "6" are used for (DESI) drugs that are not covered (refer to the Quarterly Pricing Data Definitions in section F for more specifics). All drugs are to be reported to CMS regardless of whether they are DESI drugs or not.

CMS verifies all MDRI records that are designated as DESI (codes "5" or "6") with the FDA. This assures that the DESI indication carried on the MDRI file agrees with the FDA master file. **If labelers attempt to change a DESI code, an alert message will be generated and the change will NOT be made. Labelers are told to change their system's DESI record back to the original value.**

RESERVED

FOR

FUTURE USE

...A F T E R

After CMS's quarterly URA tape is sent to the states, **three** reports are generated. These reports reflect pricing problems that <u>can only be detected during CMS's URA calculation process</u>. CMS mails the reports to labelers ASAP; however, labeler pricing data corrections WILL NOT BE USED until the next quarterly tape is sent to the states. CMS DOES NOT send "interim" URA correction files to states.

The reports generated after URA calculations are explained below.

Report 1 is "NO QUARTERLY PRICES." For all active NDCs, pricing data (AMP, and for "S" and "I" drugs, BP) are required <u>every quarter</u>. (Active NDCs have a Market Date equal to or less than the current quarter or have a termination date less than 4 quarters old.) If prices "do not change," labelers MUST report the same price as the previous quarter. If there were no sales for the quarter, labelers MUST report the price from the last quarter there were valid sales. (See section F for additional information on price reporting.)

This report shows all NDCs for which CMS has received NO pricing data or pricing data that was rejected which must be corrected and resubmitted. If labelers <u>fail to report all pricing</u>, the labeler's entire active NDC list will be reported. If labelers fail to submit pricing data for TWO CONSECUTIVE QUARTERS, they are subject to termination from the program. ☹

☜NOTE: For all NDCs on this quarterly report, the state tape contains zero in the URA field. States report zero URAs on their invoice, and labelers must compute URAs to determine the appropriate rebate amount due.

Report 2 is "NO REBATES CALCULATED." This reports NDCs requiring AMP data for a specific prior quarter. In many cases, the missing AMP is for a quarter PRIOR TO the labeler's start date. This is due to the URA calculation methodology required by OBRA '93.

For all 'S" and "I" drugs with a Market Date AFTER 09-30-90, the additional URA calculation for all quarters 93-4 and forward is NOT performed using the Baseline AMP data field and CPI-U. Rather, it is done using the CALCULATED AMP FOR THE FIRST FULL QUARTER FOLLOWING THE QUARTER THE PRODUCT WAS INTRODUCED ON THE MARKET AND THE CPI-U FOR THE MONTH PRIOR TO THAT QUARTER.

Example
NDC 89898-0110-01 is an "I" drug with a Market Date of April 20, 1992.

(Original) Baseline AMP = .12 (first day of sales AMP or selling price for that day)

Unit Type = ML
(Original) Market Date = 04/20/92
(Original) Baseline CPI-U = 139.3 (March, 92)
Labeler Start Date = 10-01-95
Reporting Quarter = 4-95

REQUIRED FROM LABELER

Calculated AMP for qtr 3-92
(USED AS) (NEW) Baseline AMP = .132453

GENERATED BY CMS

(NEW) Baseline CPI-U = 140.2 (June, 92)
(NEW) Market Date = 07-01-92

NOTE: The above three fields DO NOT replace the (original) data submitted by the labeler. Instead, they are used IN PLACE OF them. The original Baseline AMP remains in the Baseline AMP data field and is used for changes to quarters prior to 93-4.

For ALL CPI-U creep calculations beginning with 93-4, the (NEW) values are used. The labeler in this example entered the program in the 4th qtr of 1995 and supplied Baseline data and 95-4 AMP/BP prices on this NDC but did not supply pricing data for the 3rd quarter of 1992. When this report is generated it will show that the AMP from 92-3 is missing and that URAs for this NDC CANNOT be generated by CMS until it is supplied. (Section H of this guide contains a complete discussion of the URA calculation.)

Also, from time to time, a labeler finds that an NDC that should have been coded as "S" or "I" was incorrectly submitted as an "N", or vice versa. The system will **_not_** allow these changes to be made, so labelers must work with CMS drug rebate operations staff to initiate these changes. Before any change is made, CMS will require documentation from the labeler.

Report 3 is the "50/50 REPORT." This report lists all NDCs that have a URA FOR THE CURRENT QUARTER that calculates MORE THAN 50% higher or more than 50% lower than the prior quarter. The purpose of this report is to highlight pricing errors that occur mostly due to decimal alignment problems or one quarter being priced by unit and the other by package.

CMS realizes that, due to fluctuations in returns and discounts, generally with seasonal products, "peaks" and "valleys" can and do happen. Time has shown, however, that most NDCs on this report are real and valid errors. For those that are legitimate increases/decreases, CMS's report shows the URA value at the far right of the line. This assists labelers in paying invoices at the correct URA without having to perform the calculation. For those that are true pricing errors, labelers must calculate the correct URA, remit the rebate to states accordingly, and report the correct AMP/BP data to CMS **PRIOR TO or WITH** the next quarter's pricing data submission. If the pricing on the report is correct, the labeler does not need to do anything. Labelers should use the calculated URA in the far right column on the report to compute rebates. The following quarter the URA will be reported as a PPA to the states.

➥NOTE: The following pages show examples of notices sent to labelers as a result of CMS's various edit reports.

* * * N O T I C E * * *
data edit report

Attached is an edit listing of your latest Product/Pricing data submittal. Please review and follow the instructions below.

1.) Review any messages stating that **_BP_** is greater than **_AMP_**. If, in a given quarter, an **_AMP_** computes less than **_BP_**, due to large discounts or unusually high level of returns, **BP MUST** be lowered to equal **AMP**. The system has done this automatically. Please correct this record on your file.

2.) There may be **ALERT** messages stating that you attempted to change a **DESI** value. Once baseline data has been established, the **DESI** code can only be changed **UNDER DIRECTION OF THE FDA** and by a CMS Operations analyst. This change **DID NOT** take.

3.) For **PRODUCT DATA MISSING** rejects, it means that the **ENTIRE BASELINE (PRODUCT) RECORD MUST BE** re-reported, as it is **NOT** established on our master file.

4.) For **"REGULAR REJECTS"**, please follow the message. There is probably either an incorrect or unacceptable value.

5.) For **REJECTS** dealing with **Market** and **FDA Approval Dates**, please remember that their inclusion with the Baseline data became mandatory with OBRA'93.

6.) For multiple package size errors, please note that ONLY **Termination Date, Product Name, and Units Per Package Size** fields may be different. All other fields (including AMP and BP) MUST be the same for ALL package sizes of a given product. Follow all multiple package size messages carefully.

REJECT corrections must be submitted using your normal method of data submission. Correcting rejects on the attached listing and returning to us **WILL NOT CORRECT THE ERROR. ALL ERRORS ARE REJECTED BY THE SYSTEM AND MUST BE RESUBMITTED ENTIRELY BY YOU.** _BP_ corrections (_ALERTS ONLY_) have already been changed on our system and must be duplicated on your system.

Please refer to _Section G,_ of your Operations Guide for additional information.
If you have any questions, please refer to section O of your Operations guide for a list of Operations analysts.

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

Rev. 8/03

G11

****ATTENTION REQUIRED*****
(NO QUARTERLY PRICING DATA REPORT)

Enclosed is a listing of your drug products for which we did not receive prices for the calendar quarter shown. Unit Rebate Amounts (URAs) equal to zero were reported on the state files; therefore, you will have to calculate URAs and include a ROSI with your payment to each state.

If any of these NDCs have been terminated for more than four quarters, please send us a valid Termination Date. NDCs appearing on this listing either **DO NOT** contain termination dates or have termination dates less than four quarters old. Please remember that prices are due for four quarters *BEYOND* the actual quarter of termination or shelf life.

If this report contains 15 or fewer NDCs, please annotate price or termination date corrections and mail to:

Drug Rebate Operations   ATTN: Christene Holmes
c/o CMS/CMSO/FSBG/DSS   Mail Stop S3-13-15
P.O. Box 26686
Baltimore, Md 21207-0486

If there are more than 15 NDCs, please submit price/date corrections *WITH* or *BEFORE* your next quarterly submission using your *NORMAL MODE OF SUBMISSION*.

Please **DO NOT FAX** this information to us.

If you have any questions, please refer to the Operations Guide (section O) for a list of Operations analysts.

Thank you,

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

*** ATTENTION REQUIRED ***
(NO REBATES - DATA ERRORS)

When OBRA'93 was enacted, values used for Unit Rebate Amount (URA) calculations were changed. For "S" & "I" drugs having a **MARKET DATE** =/> 10-01-90, the 'additional rebate' calculation, for quarters **STARTING WITH 4-93**, is performed using the **CALCULATED** AMP for the **first full quarter** the product was on the market **IN PLACE OF** the BL/AMP. Thus, pricing (BOTH AMP/BP) for the NDCs indicated **FOR THE SPECIFIC QUARTERS REPORTED** on the enclosed report must be reported to us. This may require you to supply prices for an NDC for a quarter **prior to your starting in the rebate program.**

If there are 15 or fewer items for correction, please handwrite corrections on the listing and send it to us at the following address. If there are more than 15 corrections, please use your **NORMAL MODE FOR DATA SUBMISSION.**

Drug Rebate Operations   ATTN: Christene Holmes
c/o CMS/CMSO/FSBG/DSS   Mailstop S3-13-15
P. O. Box 26686
Baltimore, Md. 21207-0486

Please **DO NOT FAX** this information to us.

If you have any questions, please refer to the Operations Guide (section O) for a list of Operations analysts.

Thank you,

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

*** A T T E N T I O N   R E Q U I R E D ***
(50/50 REPORT)

Some of your active reported NDCs from the current quarter have been reported to the States as zero, **EVEN THOUGH YOU SUBMITTED YOUR PRICING DATA ON TIME!!** This occurs when the URA for a given NDC for this quarter is calculated to be more than 50% different (+ or -) from last quarter.

Attached is a listing of your NDCs that match this scenario. Enough historical data is included (Baseline AMP, Market Date, Last Quarter AMP/BP, etc.) for you to evaluate the problem and make corrections where applicable. If pricing is correct, **DO NOT NOTIFY US. NEXT QUARTER, CMS WILL REPORT THIS URA TO THE STATES AS A PPA. USE THE CALCULATED URA AT THE FAR RIGHT COLUMN AND COMPUTE TOTAL REBATE OWED FOR THIS NDC TO BE INCLUDED IN YOUR TOTAL REBATE TO THE STATES.** If a correction to AMP or BP is necessary, please recalculate the per unit rebate using the correct pricing and submit your rebate to the States using the CORRECTED URA. Also include a ROSI with your check to each state.

Please submit the same AMP/BP corrections to CMS with or before your next quarterly submission, using your ***NORMAL MODE FOR DATA SUBMISSION.*** If there are 15 or fewer corrections to be made, you may wish to annotate them on the listing and return to:

> Drug Rebate Operations   ATTN: Christene Holmes
> c/o CMS/CMSO/FSBG/DSS   Mailstop S3-13-15
> P.O. Box 26686
> Baltimore, Md. 21207-0486

Please **DO NOT FAX** this information to us.

If you have any questions, please refer to the Operations Guide (section O) for a list of Operations analysts.

> Thank you,

> **Vince Powell, Technical Director**
> Drug Rebate Operations
> CMS/CMSO/FSBG/DSS

CMS STATE TAPE

After the data acceptance deadline, the
MDRI system calculates URAs (about
45 days after the end of a quarter) and a
data set on magnetic medium is sent to
all state agencies. This tape/cartridge
contains two files.
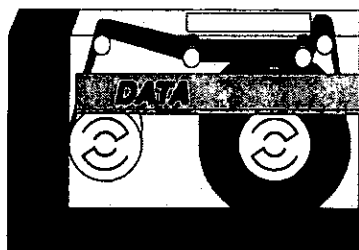
The first file is the Unit Rebate Master File, which contains:

✓ one record for each NDC on CMS's MDRI Master File
(denoted with a correction flag of "0"). Each record
contains specific Baseline data needed for identification of
the product, e.g., NDC, Product name (first 10 positions
only), Unit Type, UPPS, Therapeutic Equivalency Code,
Drug Type, Drug Category, and DESI Code. This record
also includes each NDC's URA for this quarter, or, a value
of zero;

✓ one record for Baseline changes (denoted with a correction
flag of "1"); and

✓ a pair of PPA records for prior quarter URAs recalculated
this quarter. Each pair of records contains the old URA
("2") and the new or replacement URA ("3"). PPAs are
generated when BL/AMP, Market Date, and/or prior quarter
AMP or BP are updated. The PPAs verify prior quarter
URA changes that labelers previously submitted to states.

URA FIELD

→ The correction flag "0" records that have a <u>valid URA</u> included represent NDCs that had <u>pricing data supplied</u> by labelers to CMS <u>correctly and on time</u>.

→ The correction flag '0" records <u>containing zeros in the URA field</u>, are NDCs where;

1. CMS did not receive pricing data,

2. the data was received, rejected, and not returned to CMS in time for inclusion on the quarterly tape, or

3. the pricing data was received by CMS in time, successfully passed through all edit processing and was included on the MDRI master file, BUT caused the URA to calculate as more than 50% higher or more than 50% lower than the last quarter.

Regardless of which of these three situations occur, the URA field on the CMS tape will reflect zero, and the states **MUST** report these NDCs on the invoice for all that have utilization. In turn, the labeler must compute the URA and remit the correct rebate amount to the state.

The second file sent on the state tape is the labeler name and address file. This file contains;

✓   the labeler code and name,

✓   the labeler's effective date in the program,

✓   the labeler's termination date, if applicable,

✓   the current name, address, and phone number of the labeler's contacts (legal, invoice, and technical), and

✓   an active indicator reflecting whether or not a labeler has been reinstated into the program.

States should update the above information from this file to assure that invoices are sent to the correct contact person at the correct address.

It is extremely important that labelers submit all corrections (names/addresses/phone numbers) to CMS <u>AS SOON AS THEY OCCUR</u>. Otherwise, invoices may be lost, misplaced, received late, etc. These situations can cause a delay in labelers remitting rebates resulting in the possibility of interest liability and other penalties.

ZERO UNIT REBATE AMOUNTS AND NO NDC MATCH

The CMS quarterly tape/cartridge sent to states includes one current quarter URA record for each "active" NDC on the MDRI master file. "Active" NDCs have Market Dates equal to or less than current quarter, and the Termination Date is either blank or less than four quarters beyond the current quarter.

Each record's URA contains either a value, or zeros. In either case, states compare the CMS records to their own file. If the NDC is on the state file but not on the CMS file, either the NDC is invalid or it has not yet been established on the CMS master file. For all non-matches, the state verifies the NDC by calling the labeler or CMS. In either case, validity of the NDC is determined. Valid NDCs are included on the invoice.

➡ **If the NDCs match, and the URA field contains a value**, the state must include the NDC on the invoice and report all required data elements, including the state's calculation of the rebate amount claimed (the URA X total utilization).

➡ **If the NDCs match, and the URA field contains zeros**, states MUST STILL include the NDC on the invoice and report all required data elements including total utilization; **however**, zeros are reported in the "Rebate Amount Per Unit" and "Total Rebate Amount Claimed" fields. (DO NOT treat zero URA NDCs from the CMS tape the same as nonexistent NDCs.) When NDCs with zero URAs from the CMS tape are reported on the state's invoice, labelers must calculate the URA and remit the rebate amount accordingly.
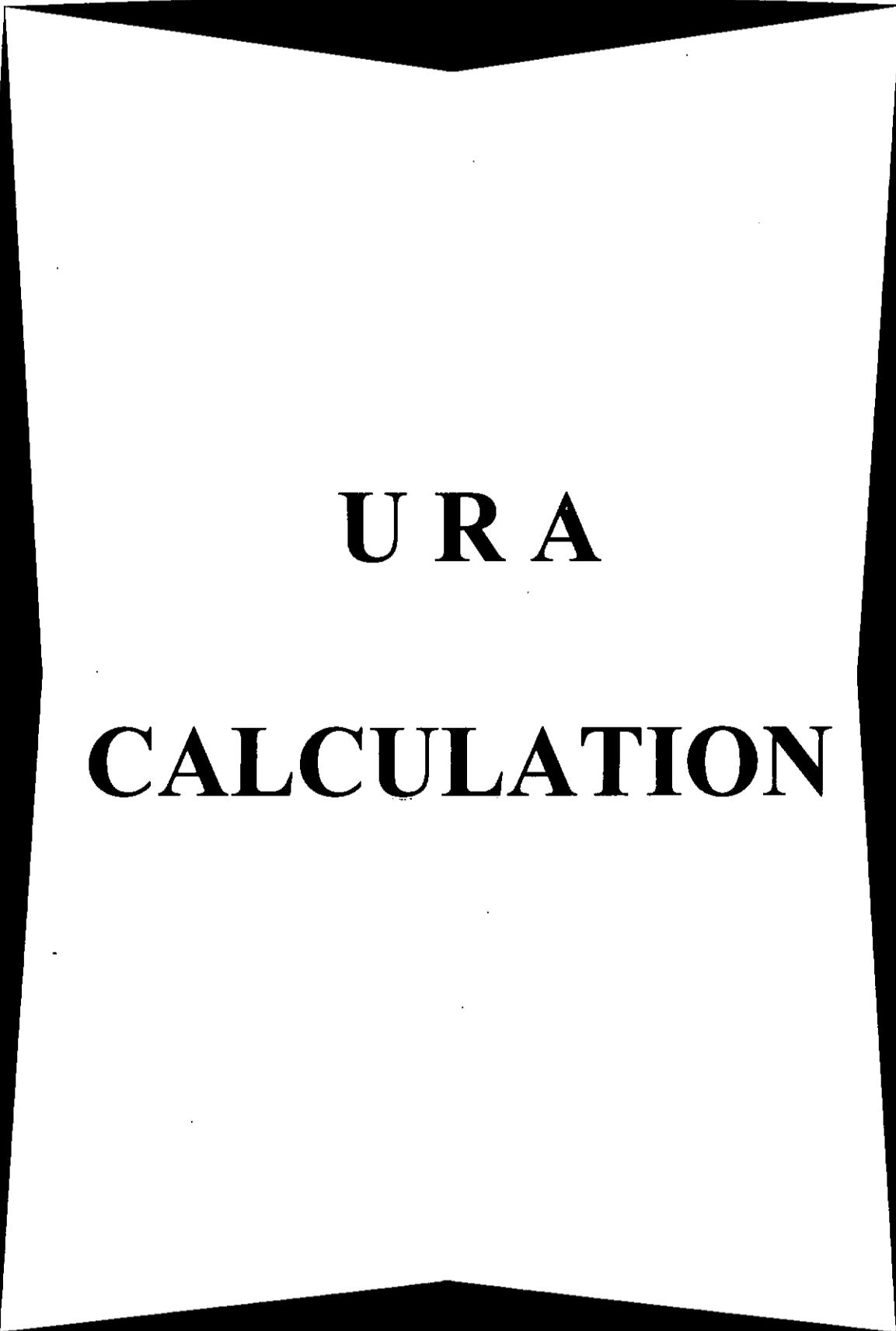
U R A

CALCULATION
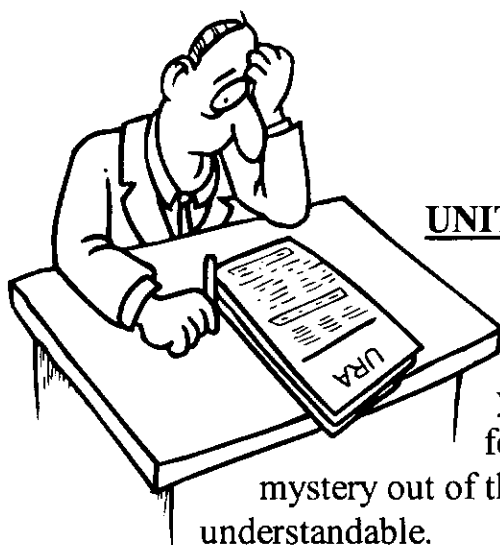
UNIT REBATE AMOUNT (URA) CALCULATION

There has been much confusion over the years about the URA calculation. The following is an attempt to take some of the mystery out of this calculation and make it more understandable.

CMS's MDRI system performs the URA calculation using the labeler's reported pricing. The percentage applied is determined by law and depends upon whether the drug product is a single source or innovator drug product ("S" or "I" drug category) or a non-innovator drug product ("N" drug category).

"N" URA CALCULATION

For "N" (non-innovator, multiple source) drugs, the URA calculation is 11% of AMP. The URA is calculated to 5 decimal places and rounded to 4.

✎Note: Prior to 01/01/94, the URA calculation was 10%.

"S" OR "I" URA CALCULATION

For "S" (single source) or "I" (innovator, multiple source) drugs, the URA calculation is performed in two steps or calculations. The first calculation provides the **basic URA**, while the second calculation provides the **additional URA**. The total URA is the basic plus the additional URA. The **TOTAL** URA figure is calculated to 5 decimal places and rounded to 4.

⇨ Step One – Basic URA

First, select the applicable rebate percentage for the corresponding time frame:

Rebate Periods	Rebate Percentage
01/01/96 to present	15.1%
01/01/95 to 12/31/95	15.2%
01/01/94 to 12/31/94	15.4%
10/01/92 to 12/31/93	15.7%
01/01/91 to 09/30/92	12.5%

Perform both "a)" and "b)":

a) AMP * the basic URA %

b) AMP – BP

The basic URA is the greater of the two results.

✎Note: For rebate periods 1991 through 1992, maximum limitations to the basic URA were applied as follows:

Year	Maximum
1992	50% of AMP
1991	25% of AMP

Several values are required to complete the additional URA calculation:

- ◆ Quarterly AMP;
- ◆ Baseline AMP and Baseline CPI-U; and
- ◆ Quarterly CPI-U.

Quarterly CPI-U is always the CPI-U value of the month <u>prior to the quarter being calculated</u>. The Baseline CPI-U value used varies depending on the product's Market Date. A quick reference for Baseline CPI-U is given in the following chart (more information on Baseline values is found further in this section).

Quarter	Market Date	Baseline AMP	Baseline CPI-U
93-4 (4th Qtr. 1993) to present	Greater than 9/30/93	AMP for 1st Qtr. After Market Date	CPI-U for month prior to 1st Qtr. after Market Date
93-4 to present	Greater than 9/30/90; less than 10/1/93	AMP for 1st Qtr. After Market Date	CPI-U for month prior to 1st Qtr. after Market Date
91-1 through 93-3	Greater than 9/30/90; less than 10/1/93	AMP for 1st day of 1st full month on the market	CPI-U for the month before 1st full month
91-1 through present	Equal or less than 09/30/90	90-3 AMP	132.7 (value for 9/90)

Perform the following calculations.

a) Baseline AMP/Baseline CPI-U

b) Result of "a)" * quarter's CPI-U

c) **If result of "b)" is less than AMP**, subtract result from quarter's AMP to get the additional URA.

   If result of "b)" is equal to or greater than the quarter's AMP, there is no additional URA to apply.

Total URA for "S" and "I" Drugs

Add any additional URA to the basic URA from step one for the total URA.

Baseline Values – Additional Information

The additional URA calculation generates many questions and can be confusing because the values applied for Baseline AMP and Baseline CPI-U vary depending on the drug's Market Date and the quarter (the URA is) calculated.

In addition to the chart above, the following is an attempt to further explain the differences.

1. **Market Date greater than 09/30/93**

    Baseline AMP equals AMP for first quarter after Market Date.

    Baseline CPI-U equals CPI-U for the month prior to the first quarter after Market Date. Note that the CPI-U calculation **is not** performed for the quarter the product is first marketed **nor** for the first quarter after Market Date.

2. **Market Date greater than 09/30/90 and less than 10/01/93 (quarters 93-4 to present)**

    Baseline AMP equals AMP for first quarter after Market Date, regardless of which day in the quarter the drug was marketed.

    Baseline CPI-U equals CPI-U for the month prior to the first quarter after Market Date.

3. **Market Date greater than 09/30/90 and less than 10/01/93 (quarters 91-1 through 93-3)**

    Baseline AMP equals AMP for the first day of the first full month the drug is on the market.

    Baseline CPI-U equals the CPI-U for the month preceding the first full month the drug is on the market. Note that the CPI-U calculation **is not** performed for the first quarter that the product is on the market.

4.   **Market Date equal to or less than 09/30/90 (all quarters 91-1 to present)**

        <u>Baseline AMP</u> equals the calculated AMP for quarter 90-3. Report this as Baseline AMP with your drug product's original Baseline data.

        <u>Baseline CPI-U</u> equals 132.7 (the CPI-U value for September, 1990)

<u>Examples: URA for "S" and "I" Drugs</u>

The URA calculation for "S" and "I" drugs can be confusing, so in the following examples we'll explore the URA calculation using the same AMP, BP and Baseline AMP, but with different market dates and quarters calculated to demonstrate the variables.

Beginning with 2001-1, the MDRI system began rounding the total URA figure from 5 decimal places down to 4, and placing zeros in the 5th and 6th decimal places. URA calculations prior to 2001-1 did not change (the URA calculation remained a figure rounded from 7 decimal places down to 6). However if a labeler changed pricing for earlier quarters and sent the change with 2001-1 data or subsequent quarterly data submissions, the pricing changes are subject to the new URA rounding standard.

All steps during the calculation are performed with the pricing at the 6th digit rounded from 7. It is only the **total** URA that is calculated to 5 decimals and rounded to 4. For purposes of the following examples, total URA rounded to 4 decimal places is used.

<u>Constant Factors in Each Example</u>:

Baseline AMP: .244795
Quarterly AMP: .357911
Quarterly BP: .299563

Please note that using the same quarterly AMP and BP in these examples will result in the same basic URA calculation outcome. As the basic URA calculation is straightforward, we will demonstrate the differences to the additional URA calculation depending on the four different variables in Quarter Calculated, Market Date, Baseline Amp, and Baseline CPI-U.

H6

Example 1

In this example the following piece of the chart provided earlier in this section is utilized, along with proper assumptions for this example.

Quarter	Market Date	Baseline AMP	Baseline CPI-U
93-4 (4th Qtr. 1993) to present	Greater than 9/30/93	AMP for 1st Qtr. After Market Date	CPI-U for month prior to 1st Qtr. After Market Date
Example Quarter	**Example Market Date**	**Example Baseline AMP**	**Example Baseline CPI-U**
01-1	10/15/95	.244795	153.5 (12/95 CPI-U)

⇨ Step 1- Basic URA

a) $.357911 * .15.1\% = .054045$ (AMP * 15.1%)
b) $.357911 - .299563 = \mathbf{.058348}$ (AMP – BP)

The basic URA is the greater of the two results, .058348.

⇨ Step 2 - Additional URA

a) $.244795/153.5 = .001595$ (Baseline AMP/Baseline CPI-U)
b) $.001595 * 174.0 = .277487$ (Result of "a)" * 12/00 CPI-U)
c) $.357911 - .277487 = \mathbf{.080424}$ (2001-1 AMP - Result of "b)")

The additional URA is .080424.

Therefore, the total URA is $.058348 + .080424 = \mathbf{.138800}$ (basic URA + additional URA).

Remember, if the result of "b)" had been greater than or equal to the quarter's AMP (.357911), no additional URA would have been applied. .080424 represents the amount in excess of allowable inflation, or additional URA, based on the CPI-U.

Example 2

In this example the following piece of the chart provided earlier in this chapter is utilized, along with proper assumptions for this example.

Quarter	Market Date	Baseline AMP	Baseline CPI-U
93-4 to present	Greater than 9/30/90; less than 10/1/93	AMP for 1st Qtr. after Market Date	CPI-U for month prior to 1st Qtr. after Market Date
Example Quarter	**Example Market Date**	**Example Baseline AMP**	**Example Baseline CPI-U**
01-1	12/14/92	.244795	141.9 (12/92 CPI-U)

⇨ Step 1 - Basic URA

a) .357911 * .15.1% = .054045   (AMP * 15.1%)
b) .357911 - .299563 = **.058348**   (AMP – BP)

The basic URA is the greater of the two results, .058348.

⇨ Step 2 - Additional URA

a) .244795/141.9 = .001725   (Baseline AMP/Baseline CPI-U)
b) .001725 * 174.0 = .300171   (Result of "a)" * 12/00 CPI-U)
c) .357911 - .300171 = **.057740**   (2001-1 AMP - Result of "b)")

The additional URA is .057740.

Therefore, the total URA is .058348 + .057740 = **.116100** (basic URA + additional URA).

Example 3

In this example the following piece of the chart provided earlier in this chapter is utilized, along with proper assumptions for this example.

Quarter	Market Date	Baseline AMP	Baseline CPI-U
91-1 through 93-3	Greater than 9/30/90; less than 10/1/93	AMP for 1st day of 1st full month on the market	CPI-U for the month before 1st full month
Example Quarter	Example Market Date	Example Baseline AMP	Example Baseline CPI-U
92-2	06/09/93	.244795	144.4 (06/93 CPI-U)

⇨ Step 1 - Basic URA

a) .357911 * .15.1% = .054045   (AMP * 15.1%)
b) .357911 - .299563 = **.058348**   (AMP – BP)

The basic URA is the greater of the two results, .058348.

⇨ Step 2 - Additional URA

a) .244795/144.4 = .001695   (Baseline AMP/Baseline CPI-U)
b) .001695 * 139.3 = .236149   (Result of "a)" * 03/92 CPI-U)
c) .357911 - .236149 = **.121762**   (2001-1 AMP - Result of "b)")

The additional URA is .121762.

Therefore, the total URA is .058348 + .121762 = **.180100** (basic URA + additional URA).

Example 4

In this example the following piece of the chart provided earlier in this chapter is utilized, along with proper assumptions for this example.

Quarter	Market Date	Baseline AMP	Baseline CPI-U
91-1 through present	Equal or less than 09/30/90	90-3 AMP	132.7 (value for 9/90)
Example Quarter	**Example Market Date**	**Example Baseline AMP**	**Example Baseline CPI-U**
00-4	09/30/90	.244795	132.7

⇨ Step 1- Basic URA

a)   .357911 * .15.1% = .054045   (AMP * 15.1%)
b)   .357911 - .299563 = **.058348**   (AMP – BP)

The basic URA is the greater of the two results, .058348.

⇨ Step 2 - Additional URA

a)   .244795/132.7 = .001845   (Baseline AMP/Baseline CPI-U)
b)   .001845 * 173.7 = .320429   (Result of "a)" * 09/00 CPI-U)
c)   .357911 - .320429 = **.037482**   (2000-4 AMP - Result of "b)")

The additional URA is .037482.

Therefore, the total URA is .058348 + .037482 = **.095800** (basic URA + additional URA).

Troubleshooting URA Calculation for "S" and "I" Drugs

Sometimes the labeler has to calculate a URA because the URA value CMS sends to the states is zero-filled. Zero URAs happen for a variety of reasons (e.g., labelers send their quarterly pricing data after CMS data cutoff, edits reject data, etc.). Some labelers perform URA calculations routinely to check against the URAs states get from the CMS tape.

Often, labelers find that the CMS URA comes out different than their calculated URA, even though they are using the formula detailed in this section of the Guide. Before calling an operations analyst, please check the following items to be sure they aren't the cause of the difference in URA calculations.

1)   Additional Rebate Calculation

The first thing to check for innovator ("S" and "I" products) is that you did the additional rebate calculation. It is the second step described in this section of the Guide, and you may owe the additional URA on top of the basic. Your calculation may be off for this simple reason.

2) Changes to Baseline AMP value

For purposes of this discussion, it is important to remember that the **Baseline AMP data field** and **Baseline AMP value** are two different things. The "Baseline AMP" data field is one of two places the Baseline AMP value is located and used to calculate the additional rebate depending on the drug's Market Date and quarter being calculated. The "Baseline AMP" data field does not always require a value as the following chart demonstrates.

Quarter	Market Date	Baseline AMP Value	Baseline AMP Value Location
93-4 (4th Qtr. 1993) – present	Greater than 9/30/93	AMP for 1st Qtr. after Market Date	Quarterly pricing record (Baseline AMP data field left blank)
**93-4 to present	Greater than 9/30/90; less than 10/1/93	AMP for 1st Qtr. after Market Date	Quarterly pricing record (Baseline AMP data field already has a value that was required from previous quarterly calculation)
*91-1 - 93-3	Greater than 9/30/90; less than 10/1/93	AMP for 1st day of 1st full month on the market	Baseline AMP data field
91-1 – present	Equal or less than 09/30/90	90-3 AMP	Baseline AMP data field

*For quarters 91-1 through 93-3, you must have a value in the "Baseline AMP" data field in order to calculate the additional rebate.

**For quarters 93-4 to present, the Baseline AMP value is no longer taken from the "Baseline AMP" data field. Rather, the Baseline AMP value used to calculate the additional rebate is the AMP you reported as quarterly pricing data for the first quarter after the Market Date.

The "Baseline AMP" Data Field already has Baseline AMP value required from previous quarterly calculations. Do not change this value, as it will be needed for any pricing changes that occur for quarters 91-1 through 93-3. This way, any pricing changes made to quarters 91-1 through 93-3 will draw the Baseline AMP value from the Baseline AMP data field, and any pricing changes made from 93-4 to present will draw the Baseline AMP value from the quarterly AMP for first quarter after Market Date.

3)   Baseline AMP & Market Date Changes

Baseline AMP Changes (for drugs with a Market Date of 10/1/93 to
present)

This applies only to drugs with a Market Date of 10/1/93 to present.
Labelers editing the drug's Baseline AMP often try to make the edit
in the Baseline AMP data field. This is incorrect. The same rule
applies to edits of Baseline AMP for these drugs as for the initial data
entry: Baseline AMP is the quarterly calculated AMP for the first
quarter after Market Date.

A change is made to the drug's quarterly pricing data, not to the
drug's baseline data to change drugs that apply to this Market Date
range. In other words, to make a change to Baseline AMP for a
product with a Market Date of 10/1/93 to present, the change must be
made to the AMP sent for the first quarter after Market Date.

Market Date Changes

Labelers occasionally enter the wrong Market Date for a drug.
CMS's MDRI system allows the labeler to correct this data field,
however, it is important to remember that Market Date changes can
change the Baseline AMP. Check for Market Date changes that
affect Baseline AMP if your URA does not match CMS's URA.

4)   Baseline CPI-U Changes Depending on Quarter Calculated

Remember that for labelers with rebate agreements effective 93-3 or
earlier, your Baseline CPI-U changes for drugs with a Market Date
greater than 9/30/90 and less than 10/1/93.

- For quarters 91-1 through 93-3 the Baseline CPI-U is the CPI-U
  from the month before the first full month the drug is on the
  market.

- Beginning in 93-4, the Baseline CPI-U is the CPI-U for the month
  prior to the first quarter after the Market Date.

5) Quarterly Data *Resubmission*

Sometimes a labeler sends their quarterly product and pricing data timely (within the 30-day period after the end of a rebate quarter), but discovers that they made a pricing mistake or omitted sending changes to product baseline data. Often, the labeler will resubmit their data with the changes.

Sometimes, the labeler takes for granted that their resubmitted data got to CMS before the rebates were calculated, when the data did not make it on time. This results in the labeler using different variables to calculate the URA than CMS actually used. Be sure that you are using the same data that made the URA tapes to the states.

6) CPI-U (Baseline and Quarterly)

Often the labeler uses the wrong CPI-U value to calculate the URA. The correct Baseline CPI-U and Quarterly CPI-U must be used to match the CMS URA.

Baseline CPI-U: Remember that the correct Baseline CPI-U depends on the quarter being calculated and the Market Date of the drug. See the chart earlier in this section for direction.

Quarterly CPI-U: Quarterly CPI-U is always the value of the month prior to the quarter being calculated.

7) Multiple Package Size Drugs

CMS sends edits to labelers that incorrectly try to use different AMPs and BPs for different package sizes of the same product. In the past, CMS sent reports to labelers, apprising them of the mistake and asking them to change the pricing accordingly. CMS would take the highest reported AMP, lowest reported BP, and use these values until the labeler sent in corrected pricing. However, labelers still sent in different AMPs and BPs, overwriting the CMS "fixes" but not correcting the problem.

In 2001, in conjunction with the redesign of the MDRI system, CMS began automatically taking the highest AMP and lowest BP without allowing the labeler to overwrite with different prices for multiple package size drugs. Labelers are sent edit reports telling them that the erroneous pricing was rejected, and that MDRI aligned prices automatically. The report also tells the labeler that the prices need to be corrected per CMS's instructions for **weighted AMP and lowest BP.**

If your URA does not match CMS's URA for a drug with multiple package sizes, be sure you are not using a value that CMS has rejected. For more information on pricing for multiple package size drugs, see section F.

THE DIFFERENCES - WHAT? WHERE? WHEN? HOW? WHY?

MARKET DATE EQUAL OR LESS THAN 09-30-90		MARKET DATE GREATER THAN 09-30-90 AND LESS THAN 10-01-93		MARKET DATE GREATER THAN 09-30-93
QTR 1/91 thru present	Baseline AMP=calculated AMP for the quarter 3-90 (and is reported with original Baseline data). Baseline CPI-U=132.7, which is the CPI-U value for September, 1990.	QTR 1/91 - 3/93	Baseline AMP=AMP for the first day of the first full month the product is on the market. Baseline CPI-U=CPI-U for the month preceding the first full month. ❧NOTE:When performing calculations, the CPI-U creep calculation IS NOT performed for the quarter the product comes on the market.	Baseline AMP=calculated AMP for the first quarter AFTER Market Date. Baseline CPI-U=CPI-U for the month prior to the first quarter after Market Date. ❧NOTE:When performing calculations, the CPI-U creep calculation IS NOT performed for the quarter the product comes on the market, NOR the first quarter AFTER the product comes on the market.
		4/93 thru present	Baseline AMP=calculated AMP for the first quarter AFTER Market Date. (This is true regardless of whether the Market Date is the first day of a quarter, last day of a quarter, or anywhere in between.) Baseline CPI-U=CPI-U for the month prior to the first quarter after Market Date. ❧NOTE:When performing calculations, the CPI-U creep calculation IS NOT performed for the quarter the product comes on the market NOR the first quarter AFTER the product comes on the market.	

INTEREST
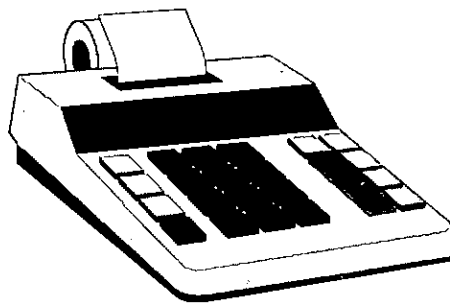
CALCULATION

INTEREST CALCULATION

The following is an overview of the interest provisions of the Medicaid Drug Rebate program. The rebate agreement requires that interest be paid or credited, when due, by the labeler or the state. For purposes of section V(b) of the National Drug Rebate Agreement, the interest rate, as specified in section 1903(d)(5) of the Act, is used. The interest rate is based on the yield of the weekly 90-day Treasury bill auction rates. The investment yield is considered the bond equivalent rate or the true discount rate.
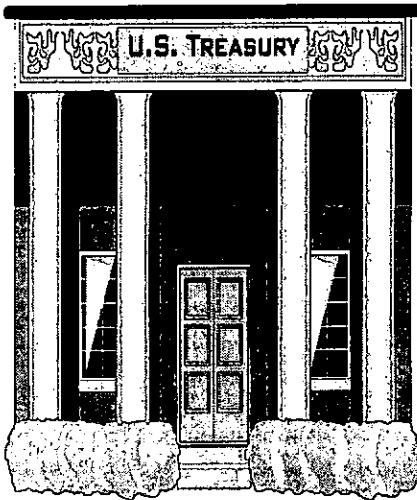
Auctions of 90-day Treasury bills are generally held each Monday. If Monday is a holiday, the Treasury Department decides whether to hold the auction on the preceding Friday or the following Tuesday. Information on the T-Bill rates is provided to states and labelers in two ways: 1) it is on the Medicaid drug rebate website at www.cms.hhs.gov/Medicaid/drugs/drughmpg.asp and is updated monthly (current month is NOT on the web); and 2) it is included in periodic state and labeler releases.

Interest Due States

1. States are due interest on all unpaid disputed rebate payments that are resolved in the state's favor through dispute resolution. A **dispute** occurs when a labeler disagrees on a specific number of its drug's units reported by the state, and provides detailed written notification of the dispute in writing. A labeler that has not paid for the disputed units that are resolved in the state's favor must pay interest that begins accruing on the 38th calendar day from the date the state receives notification from the labeler as evidenced by the postmark. Interest stops accruing and is calculated up to the postmark date of the labeler's mailed check.

   To avoid paying interest on disputes resolved in the state's favor, CMS encourages labelers to pay for disputed units timely. (See section K of the guide for more information on the dispute program.)

2.   States are due interest when a labeler makes a **late rebate payment**. A late payment is any payment made by a labeler more than 37 days after the original utilization report was postmarked (without proper dispute notification). The start and stop dates for interest are the same as explained above.

Interest Due Labelers

Certain dispute resolution-related scenarios can cause a state to owe interest credit to a labeler. Generally, when appropriate, states apply the interests as credits due the labeler.

Labelers are due interest in the following situations:

1.   Full payment with disputes

   a. The labeler pays rebates in full but disputes units timely (within 37 days after the original utilization report was postmarked);

   b. As a result of dispute resolution, any of the previously paid units are resolved in favor of the labeler; and,

   c. The state does not credit the labeler within 37 days of the resolution date as documented in the rebate resolution agreement.

2.   Full rebate of payments timely; subsequent disputes identified

   a. The labeler pays rebates for a quarter timely (no disputes are found);

   b. Sometime after the 38 days have passed, the labeler discovers a dispute for the quarter;

   c. The labeler provides written notification of the now disputed (previously paid) units;

   d. The labeler and state work through the dispute resolution process, and discover that any of the disputed units were incorrectly reported to the labeler; and,

   e. The state does not credit the labeler within 37 days of the resolution date as documented in the rebate resolution agreement.

No Interest Due

Certain adjustments made by the state and labeler have no interest implications:

- State utilization adjustments (increases or decreases)
- Labeler URA adjustments (increases or decreases) or baseline data changes that cause a PPA to a URA

Interest Start and Stop Dates

Because interest is applied daily, it's important to understand which day interest starts accruing, and which day it stops accruing.

Interest starts accruing on the 38th calendar day from the date the state receives notification of the disputed amount as evidenced by the postmark. Another way of explaining the start date for interest is that a required action (payment or credit as detailed above) is taken after the 37th day.

Interest stops accruing and is calculated up to the postmark date of the labeler's mailed check, the date the state applies credit to the labeler, or written acknowledgement to the labeler of the resolution.

At dispute resolution meetings, labelers sometimes have checks ready to give to states for prior resolutions, or are able to write a check after a successful resolution meeting. If the check includes interest, the day the state receives the check from the labeler is the day interest stops accruing.

Interest Calculation
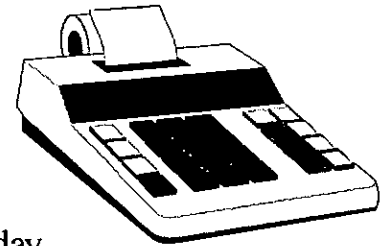
Interest is calculated using the following formula:

1. Total the yield of each weekly auction of 90-day Treasury bills during the period for which interest will be charged.

2. Divide the total from Step 1 by the number of rates (# of weeks) to determine the average interest rate.

3. Multiply the average interest rate from Step 2 by the unpaid rebate amount to obtain the amount of interest due.

4. Divide the amount of interest due from Step 3 by 365 days to obtain the daily amount of interest due.

5. Multiply the daily amount of interest due from Step 4 by the number of days beyond 37 that the late rebate payment amount, resolved rebate payment amount or interest credit amount is due to obtain total interest owed.

CALCULATION EXAMPLE (Non-Leap Year)

The state reports utilization data to a labeler postmarked 01/25/93, resulting in rebates due totaling $5,400 for the 4th quarter of 1992. The labeler mails a check for $4,400 postmarked within 37 days after receipt of the utilization data, and disputes units representing the remaining $1,000. Interest starts accruing on 3/4/93, which is the 38th day after the state's utilization data is postmarked. Subsequently, the labeler and state resolve the dispute in the state's favor, and the labeler mails a check for the remaining $1,000 postmarked on 4/2/93.

In this example, interest is accrued for the period 3/4/93 through 4/1/93. The check from the labeler must include the principal of $1,000 plus interest calculated as follows:

AUCTION DATES AND YIELD RATES   (Obtain yield rates
    3/01/93   3.035%   (bond equivalent rates)
    3/08/93   3.043%   for period involved.)
    3/15/93   3.064%
    3/22/93   3.003%
    3/29/93   3.022%

Step 1 -   Total the yield rates of each weekly auction of 90-day Treasury Bill.   Total: 15.167%

Step 2 -   Divide the total from Step 1 by the number of rates to determine the average interest rate. 15.167% divided by 5 = 3.0334% Average Interest Rate.

Step 3 -   Multiply average interest rate by amount of unpaid rebate. $1,000 x 3.0334% = $30.33 Amount of Interest Due.

Step 4 -   Divide the amount of interest due by 365 days to obtain the amount of interest due per day. $30.33 divided by 365 days = .08310 = Amount of Interest Due Per Day.

Step 5 -   Multiply daily amount of interest due per day by the number of days the unpaid rebate amount is outstanding. $.08309 x 29 days (3/4/93-4/1/93) = $2.41 Total Interest Due.

Therefore, the check amount, including interest, should be $1,002.41

Unpaid Interest Becomes Principal

When a labeler makes a late rebate payment or pays a dispute resolved in the state's favor after 37 days of the resolution agreement date, the labeler must pay interest. If the labeler pays without including the interest due, unpaid interest becomes principal and interest accrues on the new principal amount beginning on the 38th day the interest began accruing.

Tolerance Threshold for Interest

If the state determines that its administrative costs to recover interest owed by a labeler exceed the interest amount due, the state may apply up to a $50 tolerance level per labeler to interest payments. Application of this tolerance is optional for states; they may collect or waive interest amounts at or below the tolerance level. In all cases where a state chooses to apply tolerance levels, both the state and the labeler should maintain adequate documentation.

$ Prior Quarter
Pricing Changes
For AMP or BP $

PPAs

```
          E
        N
      I           E
    L     P     G
  E     M     N
B   S     A     A
  A     C   H
B           C
```

MARKET   DATE
CHANGES
FOR   OBRA'93
FORWARD

PRIOR PERIOD ADJUSTMENTS
(PPAs)

Prior period adjustments are URA changes sent to states on the CMS quarterly tape. URA changes occur when labelers submit changes to the MDRI pricing file:

1. For changes in AMP and/or BP for a **prior** quarter;
2. For Baseline AMP changes; or
3. For Market Date changes affecting URAs (see section H for more information).

✹✹✹ <u>Utilization Changes Made By States</u> ✹✹✹
✹ ✹ <u>ARE NOT PPAs.</u> ✹✹

<u>Labelers recalculating URAs must also adjust the previous rebate amount paid</u> based on the relevant quarter's utilization. When labelers send CMS a change that affects the previously reported price, the labeler <u>must recalculate</u> the URA for all quarters affected by the change. Labelers must use the PQAS to report the recalculated URA and other required data elements to all states that utilized the NDC. (The PQAS is discussed in section F of this guide.)

Regardless of when a pricing change is discovered, labelers must complete the PQAS using the correct URA, thereby accurately adjusting any prior rebate payments affected by the pricing changes.

CMS updates the MDRI master file with the labeler's changes and recalculates URAs for affected quarters. CMS's next quarterly URA tape will contain PPA records the state matches to the PQAS submitted by the labeler. The tape and the PQAS should match.

Sometimes labeler changes miss the data deadline for inclusion on the current CMS tape. Labelers discover a pricing problem for a prior quarter after CMS sends the URA tape to the states, and before the labeler processes payments to the states. When this happens, the labeler's PQAS reports the **current** URA for the relevant quarter. The state receives the PPA from CMS the following quarter.

States must allow two quarters for the labeler's PQAS-reported URA adjustment to appear as a PPA on the CMS tape. In the interim, states use the labeler's data reported on the PQAS. After two consecutive quarters, any discrepancies between the tape and the labeler's PQAS are resolved between the state and the labeler, if possible. An impasse should be reported to CMS for resolution.
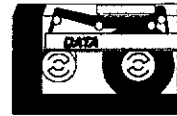
PPA LISTING (OPTIONAL)

States may attach a PPA listing to their invoices for **informational purposes only**. No dollar amount associated with this PPA listing are claimed on the quarterly invoice.

STATE PPA LISTING V. LABELER PQAS

Labelers should check state PPA lists against their own PQAS URA adjustments. However, labelers should remember that the state's information will be one quarter behind due to pricing changes sent past the data deadline for inclusion on the tape. In this instance, labelers are required to remit rebate payments based on the current URA, which may not match the state's PPA listing until the following quarter.

The same is true for the state. The labeler's PQAS-reported URA changes may not match CMS's quarterly tape until two consecutive quarters have passed. Both parties should be able to verify PPA information within two quarters.

THIS ➡
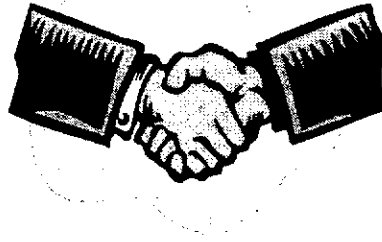
DISPUTE
RESOLUTION
PROGRAM

NOT THIS ➡

DISPUTE RESOLUTION PROGRAM
(DRP)

As discussed in earlier sections of this guide, states are required to report their quarterly utilization to labelers. The labelers then send states a rebate payment.

However, labelers sometimes question the state's utilization accuracy for various reasons. When a labeler has reason to suspect an error in state utilization reporting of their product, it is called a dispute.

The labeler who disputes units of their drug invoiced by the state has two options in their dispute approach:

1. The labeler can pay the state for the disputed items, then work with state representatives to resolve the dispute. CMS recommends this option to labelers that don't want to pay interest in the event the dispute is subsequently resolved with the labeler owing rebate on any of the disputed units. (For more information on interest, see section I of this guide.)

2. The labeler can pay the state for all units not in dispute, but withhold payment for the disputed units. Labelers that choose this option may owe interest if the disputed units are later resolved as correctly reported by the state.

CMS encourages states and labelers to work in partnership to resolve disputes. However, we recognize that there are disputes that cause the two parties to come to an impasse or that require technical clarification on related drug issues.

CMS's DRP Team is available to help move the dispute through to resolution. Several DRP national meetings are held each year, and we encourage all states and labelers with disputes to attend these meetings. The DRP national meeting schedule is announced in a program release to all states and labelers as soon as meeting dates are set. For more information on DRP meetings, call Diane Dunstan on (303) 844-7040.

More comprehensive information on working through the DRP process is available in the *Best Practices Guide for Dispute Resolution*, which was sent to all states and labelers in 1999.

For questions on disputes, contact the CMS Regional Office (RO) DRP Coordinator for the state with the dispute. A list of RO/central office contacts is located in section O of this guide.
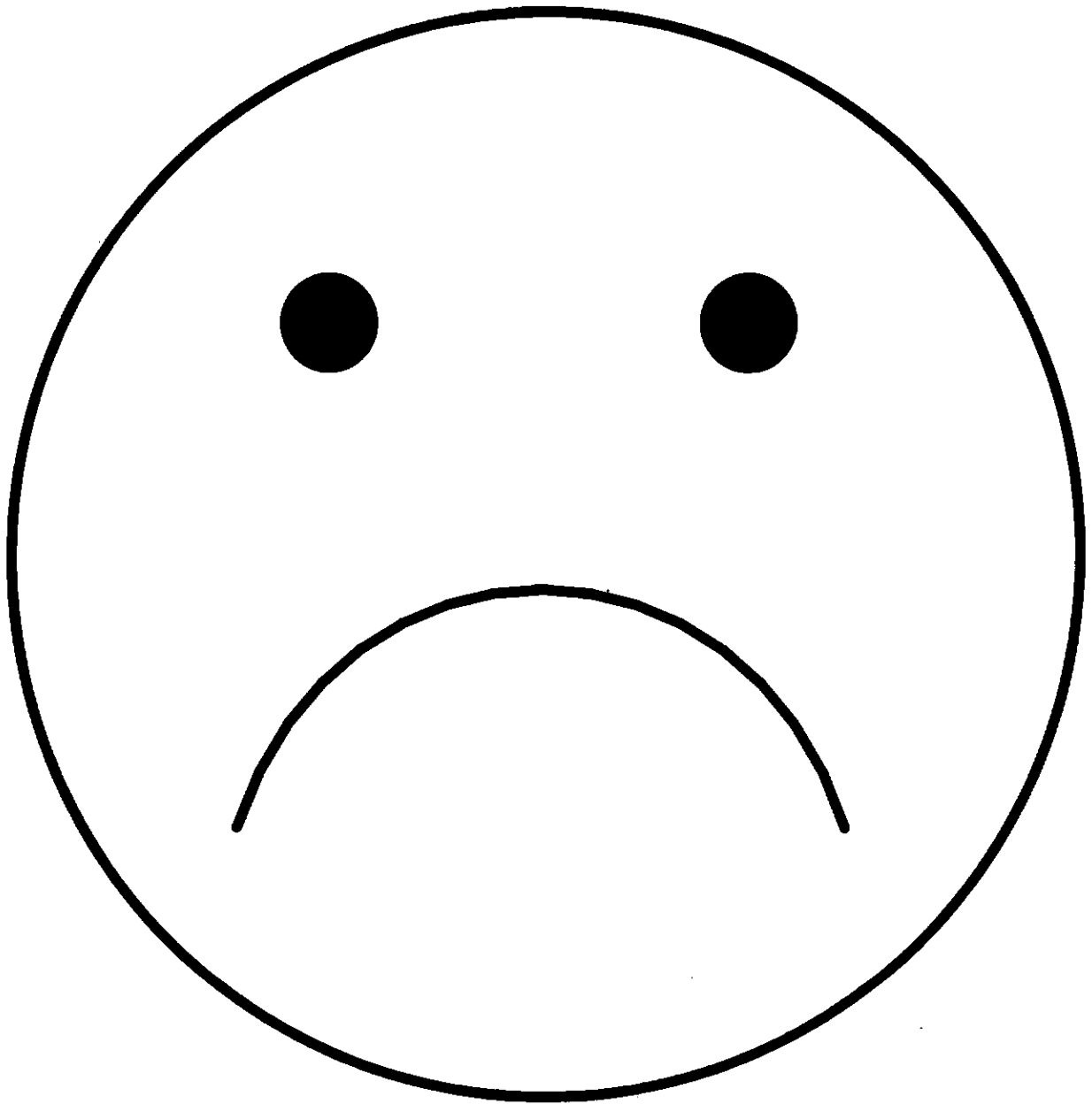
TERMINATION

TERMINATION
FROM THE
MEDICAID DRUG REBATE PROGRAM

States may choose to cover outpatient drugs under the Medicaid program. If a state opts to cover outpatient drugs, section 1927 of the Act applies to the state.

States must cover all of a participating labeler's drugs, with certain exceptions, and the Federal government shares in the expense. In return, labelers must pay rebates to states. The Medicaid Drug Rebate Agreement and section 1927(b)(4)(B) of the Act describe the circumstances under which a labeler can be terminated from the program. Briefly, a labeler may be terminated from the program for failure to submit quarterly pricing data to CMS, nonpayment of rebates, and for other good cause. The specifics of the termination process are outlined below.

TERMINATION BY CMS

CMS may terminate a labeler's rebate agreement for violations or other good cause. If termination action is taken, the labeler may request a hearing.

If a labeler fails to submit quarterly pricing data, CMS will issue a termination warning letter. This letter states that the labeler will be terminated unless CMS receives the missing data within a specified timeframe. The termination is effective for the quarter that begins no earlier than 60 days from the letter's date. CMS's termination warning letter is the last attempt to establish labeler compliance with the rebate agreement and obtain missing pricing data. It is issued after telephone requests are unheeded.

If a labeler is terminated for other reasons, a similar warning letter describing the termination cause is issued. The letter also includes a time period for the labeler to correct the problem and provides an opportunity to request a hearing.

TERMINATION APPEAL PROCESS

A labeler can request a termination hearing. The termination warning letter specifies the hearing request process. If a labeler elects to appeal termination, the written appeal must be received by CMS within 45 days of the termination warning letter date. A copy of the termination warning letter, clear indication of the labeler's intent to appeal the termination, and a brief explanation of the reason the labeler believes the termination is incorrect should be included in the appeal request.

The labeler's written notice of appeal may be hand delivered or mailed to the following address:

> Centers for Medicare & Medicaid Services
> Center for Medicaid and State Operations
> Drug Rebate Program
> Mail Stop S3-13-15
> 7500 Security Boulevard
> Baltimore, Maryland 21244

TERMINATION BY THE LABELER

A labeler may terminate its drug rebate agreement for any reason with prior written notice to CMS.

If a labeler chooses to terminate its agreement any time during the agreement period, the termination is effective the first day of the first calendar quarter beginning 60 days after the labeler's written notice requesting termination.

If a labeler chooses not to automatically renew its drug rebate agreement, the effective termination date is the ending date of the agreement provided the labeler gives written notice of intent not to renew. The notice of intent must be received at least 90 days before the end of the current agreement period.

FINAL TERMINATION

When a termination action becomes final, CMS notifies each state that FFP is not available for the labeler's drug products beginning with the effective date of the termination.

> ✒NOTE: Any termination from the drug rebate program WILL NOT affect rebates due <u>before</u> the effective date of termination.

RE-ENTERING THE REBATE PROGRAM

Once terminated, a labeler is prohibited from re-entering the drug rebate program until one calendar quarter after the effective date of the termination. To re-enter the rebate program, a labeler must complete and sign a **new** Medicaid Drug Rebate Agreement. Any problems that caused a labeler's involuntary termination must be resolved prior to re-entering the program, e.g., any missing pricing data must be submitted, rebates paid, etc.

NO TERMINATIONS BY STATES

States can not terminate labelers from the Medicaid Drug Rebate Program. CMS retains the delegated authority to take termination action.

States should advise CMS of labelers not paying rebates, properly disputing utilization, or of drug rebate agreement violations. CMS investigates state concerns and determines the appropriate action required.

FORMS

This section of the guide contains copies of all the forms (excluding instructions, etc.) required in the Medicaid Drug Rebate Program. The following is a brief description of these forms.

LABELERS

Form CMS-367, }
367a, and 367c

Form 367 is used to remit quarterly pricing data to CMS. Form 367a is contact information, (367b is no longer required), and 367c is a data media option form.

Form CMS-304 }
(ROSI)

Used to reconcile and explain the remittance of rebate payments to states for the current quarter.

Form CMS-304a }
(PQAS)

Used to reconcile and explain prior quarter actions/payments to states.

STATES

Form CMS-368 }

Used to report contact information. (The supplemental data sheet is no longer required.)

Form CMS-R-144}
(Invoice)

Used to report utilization data to labelers and CMS.

NOTE: Specific information regarding these forms can be found in this guide by referencing the Index under "Forms."

LABELER QUARTERLY PRICING DATA
PAPER REPORTING FORMAT

QUARTERLY REPORT FOR __/_____   **LABELER CODE** _____
                                 Q YYYY

PRODUCT CODE: __ __ __ __   PACKAGE SIZE CODE: __ __

DRUG CATEGORY: __
THERAPEUTIC EQIV. CODE: __ __
DESI INDICATOR: __
AVERAGE MANUFACTURER PRICE: __ __ __ __ __ . __ __ __ __ __ __
BEST PRICE: __ __ __ __ __ . __ __ __ __ __ __
DATE ENTERED MARKET: __ __ __ __ __ __ __ __
BASELINE AMP: __ __ __ __ __ . __ __ __ __ __ __
TERMINATION DATE: __ __ __ __ __ __ __ __
CORRECTION FLAG: __ (Activate for Baseline Data and/or Pricing Data corrections.)
UNIT TYPE: __ __ __
UNITS PER PACKAGE SIZE: __ __ __ __ __ __ __ . __ __ __
FDA APPROVAL DATE: __ __ __ __ __ __ __ __
DRUG TYPE: __
PRODUCT NAME: __
__ __
__ __ __ __ __

****

PRODUCT CODE: __ __ __ __   PACKAGE SIZE CODE: __ __

DRUG CATEGORY: __
THERAPEUTIC EQIV. CODE: __ __
DESI INDICATOR: __
AVERAGE MANUFACTURER PRICE: __ __ __ __ __ . __ __ __ __ __ __
BEST PRICE: __ __ __ __ __ . __ __ __ __ __ __
DATE ENTERED MARKET: __ __ __ __ __ __ __ __
BASELINE AMP: __ __ __ __ __ . __ __ __ __ __ __
TERMINATION DATE: __ __ __ __ __ __ __ __
CORRECTION FLAG: __ (Activate for Baseline Data and/or Pricing Data corrections.)
UNIT TYPE: __ __ __
UNITS PER PACKAGE SIZE: __ __ __ __ __ __ __ . __ __ __
FDA APPROVAL DATE: __ __ __ __ __ __ __ __
DRUG TYPE: __
PRODUCT NAME: __
__ __
__ __ __ __ __ __

CMS-367 (Exp. 07/31/03
OMB No. 0938-0578)   **M3**

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT – Person to contact for legal issues concerning the rebate agreement

NAME OF CONTACT

AREA	PHONE NUMBER	EXTENSION

NAME OF CORPORATION

STREET ADDRESS

CITY	STATE	ZIP CODE

INVOICE CONTACT – Person responsible for processing invoice utilization data

NAME OF CONTACT

AREA	PHONE NUMBER	EXTENSION

NAME OF CORPORATION

STREET ADDRESS

CITY	STATE	ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

CMS-367a (Exp. 07/31/03)
OMB No. 0938-0578

M4

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT – Person responsible for sending and receiving data

NAME OF CONTACT

AREA	PHONE NUMBER	EXTENSION

FAX #:

EMAIL Address:

NAME OF CORPORATION

STREET ADDRESS

CITY	STATE	ZIP CODE

Note: If more than one labeler code, attach one sheet for each code.

CMS-367a (Exp. 08/31/06)
OMB No. 0938-0578

Rev. 11/04   **M5**

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

PLEASE INDICATE THE MEDIA PREFERENCE YOU INTEND TO USE FOR TRANSMITTING DATA IDENTIFIED IN APPENDIX A OF THE REBATE AGREEMENT TO CMS. THE INSTRUCTIONS, TECHNICAL SPECIFICATIONS AND MATERIALS APPROPRIATE TO THE OPTION SPECIFIED WILL BE MAILED TO YOU UPON RECEIPT OF YOUR SIGNED AGREEMENT.

☐   **OPTION 1**   **TELECOMMUNICATIONS**
Transmit data through telecommunications. Record formats are attached. Upon election of this option, CMS will mail additional instructions, including the "Dial In" number of the CMS electronic mailbox.
(See next pages for Telecommunications format.)

☐   **OPTION 2**   **3 ½" HD DISKETTE**
Upon election of this option, a preprogrammed diskette will be mailed to you, along with instructions.

CHECK **ONLY ONE (1)** OF THE FOLLOWING:

☐   WINDOWS 3.11

☐   WINDOWS 95

☐   **OPTION 3**   **PAPER**
For manufacturers with five or fewer drug products. The form for submitting data is attached.
(See next pages "Paper Reporting Format")

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

THIS PAGE IS RESERVED

FOR FUTURE USE

RECONCILIATION OF STATE INVOICE

PAGE _____ OF _____

COMPANY NAME _____   LABELER CONTACT _____   STATE _____

LABELER CODE _____   PHONE _____   INVOICE NO. _____

QUARTER COVERED _____   FAX _____   DATE _____

PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE PER UNIT	ADJUSTED REBATE PER UNIT	U N I T S				ADJM CODE	DISP CODE	D O L L A R S			
				UNITS INVOICED	ADJUSTED UNITS + or -	LABELER DISPUTED UNITS	UNITS PAID			REBATE AMOUNT INVOICED	INVOICE CORRECTION AMOUNT + or -	WITHHELD INVOICE AMOUNT	REBATE AMOUNT PAID
A	B	C	D	E	F	G	H	I	J	K	L	M	N
TOTALS													

Plus Interest Payment

TOTAL REMITTANCE _____

CMS-304 (Exp. 5/31/04)

OMB No. 0938-0676

Page M8

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(for reconciling unit changes, disputed units, and PPAs)

COMPANY NAME _____ LABELER CONTACT _____ STATE _____

LABELER CODE _____ PHONE _____ INVOICE NO. _____

QUARTER COVERED _____ FAX _____ DATE _____

				U	N	I	T	S	D	O	L	L	A	R	S		
PRODUCT PACKAGE CODE	PRODUCT NAME	ORIGINAL REBATE PER UNIT	CURRENT REBATE PER UNIT	ORIGINAL UNITS INVOICED	CURRENT UNITS TO DATE	PRIOR UNITS PAID	CURRENT UNITS PAID TO DATE	PRIOR UNITS DISPUTED	CURRENT UNITS DISPUTED TO DATE	ORIGINAL AMOUNT INVOICED	REVISED INVOICE AMOUNT	PRIOR AMOUNT PAID	CURRENT AMT PAID TO DATE	AMT PAID THIS TRANS		ADJM CODE	DISP CODE
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O		P	Q
TOTALS																	

Plus Interest Payment

Total Remittance

CMS-304a (Exp.5/31/04)

OMB No. 0938-0676

Page M9

MEDICAID DRUG REBATE PROGRAM
STATE AGENCY CONTACT FORM

STATE AGENCY NAME

TECHNICAL CONTACT – Person responsible for sending and receiving data.

NAME OF CONTACT

	AREA	PHONE NUMBER	EXTENSION
FAX	AREA	PHONE NUMBER	EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY	STATE	ZIP CODE

PROGRAM POLICY CONTACT – Person responsible for policy decisions.

NAME OF CONTACT

AREA	PHONE NUMBER	EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY	STATE	ZIP CODE

MEDICAID DRUG REBATE PROGRAM
STATE AGENCY CONTACT FORM

STATE AGENCY NAME

REBATE CONTACT – Person responsible for invoice and receipt of rebate payments.

NAME OF CONTACT

AREA	PHONE NUMBER	EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY	STATE	ZIP CODE

DATE: ___/___/_____
MM DD YYYY

STATE OF _____
_____ (Medicaid Agency)

PAGE ___ OF ___

Source: State Agencies
Target: Manufacturers

MEDICAID DRUG REBATE INVOICE

Manufacturer: _____
Address: _____

City: _____ State: ____ Zip: _____

STATE CODE: ____   INVOICE NO.: _____
PERIOD COVERED: _____ (QYYYY)

NDC Number	Drug Name	Rebate Amount Per Unit	Total Units Reimbursed	Total Rebate Amt. Claimed	No. of Scripts	Total Reimb. Amount	Corr Flag
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____
_____	_____	_____	_____	_____	_____	_____	____

TOTALS: _____   *_____

Note: NDC# = Labeler Code (5#s)
Product Code (4#s)
Pkg. Size Code (2#s)

*Please remit this amount to: _____ (Medicaid Agency)
Address: _____

Attn:

Late Breaking News

CMS

PROGRAM

RELEASES

CMS PROGRAM RELEASES

Since the start of the Medicaid Drug Rebate Program, CMS has had an ongoing need to communicate with labelers and states. Lack of media compatibility among 500+ labelers and 51 states makes hardcopy mailed program releases the only uniform medium for initial communication.

Releases provide various types of policy, technical, systems, and operational information. CMS provides a Topical Index in each release which lists alphabetically the program release topics. The Topical Index includes current release topics as well as all prior release topics and the release number(s) in which the topics are found. Each release also provides a list of weekly U.S. T-Bill Discount Rates for labelers to calculate interest.

CMS sends releases to the technical contact specified by the state and labeler. We know that this person is usually not responsible for ALL drug rebate program functions. **Therefore, CMS encourages everyone to share the releases with all personnel involved in the drug rebate program.**

OBTAINING COPIES OF PROGRAM RELEASES

Generally, within a week of issuing a release to either state agencies or drug labelers, CMS uploads the release to the INTERNET.

For states, labelers, and private individuals with access to the Internet, the program releases are available at:

www.cms.hhs.gov/Medicaid/drugs/drughmpg.asp

✎**NOTE:**   CMS no longer provides the drug rebate releases for incorporation to the CD-ROM.

The following pages show examples of the text of a state and labeler release.

MEDICAID DRUG REBATE PROGRAM   **RELEASE #**

For State Medicaid Directors

REMINDER – HCFA TAPE NO LONGER CONTAINS PHS COVERED ENTITIES

Beginning with the 1Q2001 tape, there will not be a file containing a list of PHS covered entities. To obtain this data you must access HRSA's website, www.hrsa.gov/odpp. Notice of this change was previously given in Release Number 101, dated September 14, 2000.

REMINDER – ROUNDING OF UNIT REBATE AMOUNT (URA)

As stated in Release Number 100, dated July 11, 2000, the state tape now will contain URAs which are calculated to the 5th decimal place, rounded to the 4th, and have zeros pad positions 5 and 6. This change is effective with the 1Q2001 tape due to states around May 15.

ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period January 3, 2000, is attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide.

David McNally, Deputy Director
Finance, Systems and Quality Group

N4

MEDICAID DRUG REBATE PROGRAM   RELEASE #

Bulletin

For
Participating Drug Manufacturers

LIMITED REVISIONS TO THE OPERATIONAL TRAINING GUIDE

In an effort to maintain an accurate drug rebate agreement on the Internet, we have updated the signature line and accordingly are replacing section C in the Operational Training Guide. Attached are updated pages for section C and section M of the guide.

The agreement has been updated to reflect the current HCFA address and organizational structure. Also, we have deleted our cover letter to the agreement. Enclosure B to the agreement (pages M4-M7 in the guide) has been updated to eliminate the page that indicates which states have signed rebate agreements with labelers.

ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period June 7, 1999, is attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide.

David McNally, Deputy Director
Finance, Systems and Quality Group

N5

GIVE US A CALL

CMS
DRUG REBATE
DIRECTORY
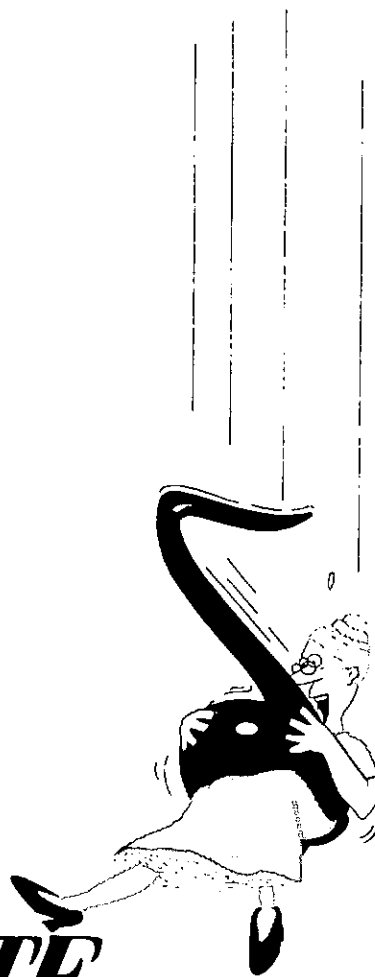
DROP US A NOTE

CMS DRUG REBATE PROGRAM

Area Code 410

OPERATIONS

Cindy Bergin	786-1176	cbergin@cms.hhs.gov
Tamara Bruce	786-1519	tbruce@cms.hhs.gov
Chris Holmes	786-3328	cholmes@cms.hhs.gov
Karen Leshko	786-1291	kleshko@cms.hhs.gov
Vince Powell (Technical Director)	786-3314	vpowell@cms.hhs.gov
Sue Williams	786-3334	swilliams1@cms.hhs.gov

POLICY

Kim Howell	786-6762
Christina Lyon	786-3332
Katiuscia Potier	786-1947
Gail Sexton	786-4583
Marge Watchorn	786-4361
Larry Reed (Technical Director)	786-3325

SYSTEM MAINTENANCE

E-mail inquiries to: MDRtech@cms.hhs.gov

DISPUTE RESOLUTION PROGRAM

Sue Gaston	786-6918	sgaston@cms.hhs.gov
Tamara Bruce	786-1519	tbruce@cms.hhs.gov
Diane Dunstan	303-844-7040	ddunstan@cms.hhs.gov

FAX
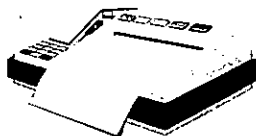
786-0390 – Operations
786-8534 - Policy

WEBSITE   www.cms.hhs.gov/medicaid/drugs/drughmpg.asp

CMS MEDICAID DRUG REBATE
MAILING ADDRESSES

Regular Mail ➜ CMS, CMSO
Drug Rebate Program
P.O. Box 26686
Baltimore, Maryland   21207
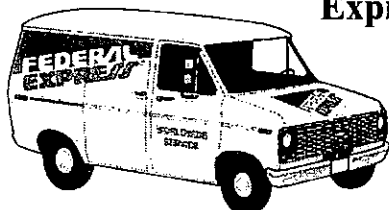
Express Mail ➜ CMS, CMSO
Drug Rebate Program
Mail Stop S3-18-03
7500 Security Boulevard
Baltimore, Maryland   21244

NOTE: PLEASE DO NOT USE the express mail address to send general correspondence to CMS.   The use of this mail stop for general correspondence will delay its delivery to the appropriate individual.

CMS DRUG REBATE PROGRAM
PRIMARY FUNCTIONS/CONTACT PERSON

Primary Function	Contact Person
Contact Changes (labelers and states)	Karen Leshko
CPI-U Values	Karen Leshko
Data Edit Reports	Karen Leshko
	Vince Powell
Data Submission (labelers)	Karen Leshko
	Vince Powell
Data Submission (states)	Vince Powell
Diskette Installation/Problems	MDRtech@cms.hhs.gov
Dispute Resolution	Sue Gaston
	Tamara Bruce
HIV/AIDS Drugs	Marge Watchorn
Interest Calculation	Vince Powell
	Tamara Bruce
Invoice	Sue Williams
Policy Issues (general)	Claire Hardwick, Kim Howell, Christina Lyon, Gail Sexton, Maria (Cora) Tracy, Marge Watchorn
Prior Quarter Adjustment Statement	Sue Williams
Prior Period Adjustments	Vince Powell
Pricing Data/Product Elements	Vince Powell
Reconciliation of State Invoice	Sue Williams
State Tape	MDRtech@cms.hhs.gov
T-bill Rates	Karen Leshko
Training Guide	Sue Williams
VHCA/340B Drug Pricing	Marge Watchorn

Regional Office Drug Rebate Dispute Resolution Program
Coordinators

Analysts	E-mail	Phone #	States
Region I – Boston Ray Porter	rporter@cms.hhs.gov	(617) 565-1260	Connecticut, New Hampshire, Maine, Massachusetts, Rhode Island, Vermont
Region II – N.Y. Robert Cochrane	rcochrane@cms.hhs.gov	(212) 264-3885	New York, New Jersey
Region III-Phil. Jennifer Quinn	jquinn@cms.hhs.gov	(215) 861-4174	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia
Region IV - Atlanta Jessie Spillers Elaine Elmore	jspillers@cms.hhs.gov eelmore@cms.hhs.gov	(404) 562-7418 (404) 562-7408	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
Region V - Chicago *	Until further notice please contact RO VIII		Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
Region VI - Dallas Mike Jones	mjones7@cms.hhs.gov	(214) 767-6279	Arkansas, Louisiana, New Mexico, Oklahoma, Texas
Region VII - Kansas City Frank Campbell	fcampbell@cms.hhs.gov	(816) 426-5925 x3310	Iowa, Kansas, Missouri, Nebraska
Region VIII – Denver *Diane Dunstan	ddunstan@cms.hhs.gov	(303) 844-7040	Colorado, Montana, North Dakota, South Dakota, Wyoming
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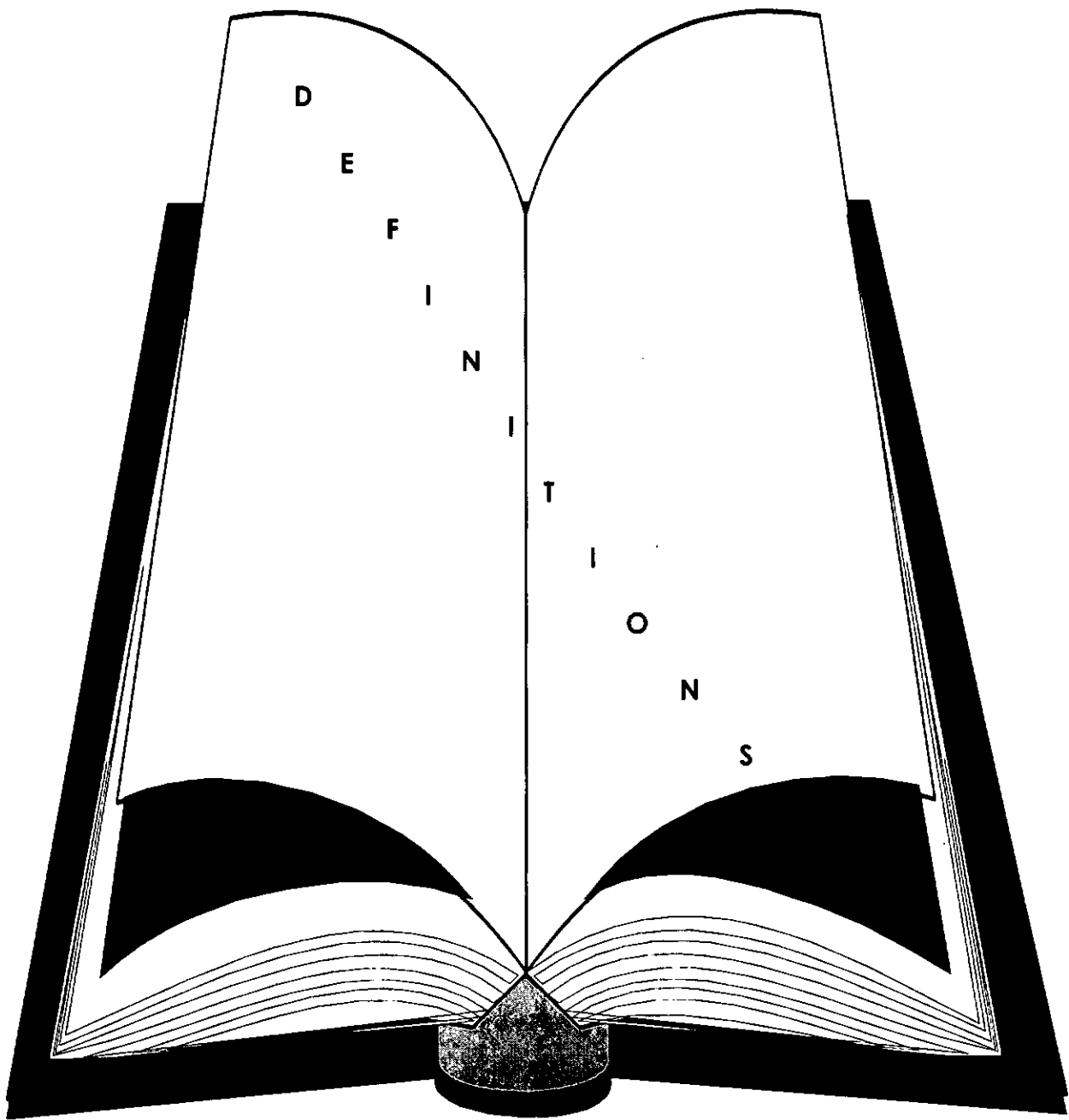
DEFINITIONS

PROGRAM DEFINITIONS

The following definitions are programmatic and operational in nature. Some definitions were taken from the statute and interpreted herein. Specific <u>data</u> definitions related to reporting requirements, e.g., pricing data, ROSI/PQAS forms, are contained in their respective sections of this guide.

Average Manufacturer Price (AMP) means, with respect to a covered outpatient drug of the labeler for a calendar quarter, the average unit price paid to the labeler for the drug in the states by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the labeler's package sizes for each covered outpatient drug sold by the labeler during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The AMP for a quarter must be adjusted by the labeler if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

Baseline Consumer Price Index-Urban (CPI-U) is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

Baseline AMP means that for all single source ("S") and innovator ("I") drugs with a market date earlier than 10-01-1990, it is the calculated AMP for the July-September, 1990 quarter. For drugs approved by the FDA from 10-01-1990 through 09-30-1993, it is the AMP for the first day of the first full month in which the drug was marketed. Beginning with "S" and "I" drugs marketed on or after 10-01-1993, Baseline AMP is to be left blank.

Best Price means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the labeler sells the covered outpatient drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities, or governmental entities within the states (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods contingent on any purchase requirements, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

Excluded from the calculation of best price are prices charged to the following entities: the Indian Health Service; the Department of Veterans Affairs; a state home receiving funds under section 1741 of title 38, United States Code; the Department of Defense; the Public Health Service (PHS) or any entity described in section 340B(a)(4) of the PHS Act and as further specified in Federal Register notices; the Federal Supply Schedule; and, a state pharmaceutical assistance program.

Bundled Sale refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

Consumer Price Index-Urban (CPI-U) means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

Covered Outpatient Drug will have the meaning as set forth in Section 1927(k)(2), (k)(3), and (k)(4) of the Act, and with respect to the labeler includes all such drug products meeting this definition. For purposes of coverage under the drug rebate agreement, all of those covered outpatient drugs are identified by the manufacturer's labeler code segment of the NDC number. Certain covered outpatient drugs, such as specified by Section 1927 (d)(1)-(3) of the Act, may be restricted or excluded from Medicaid payment at state option but shall be included by the labeler for purposes of the drug rebate agreement.

Depot Price means the price(s) available to any depot of the Federal Government for purchase of drugs from the labeler through the depot system of procurement.

Federal Financial Participation means the Federal share of state expenditures for services, training, and administration under an approved State Plan for medical assistance.

Individual State Agreement means an agreement between a state and a labeler authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

Innovator Multiple Source Drug will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all covered outpatient drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug (ADA) Approval. A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

Labeler will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of the drug rebate agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug.

Market Date means the date a drug was first available for sale by a labeler in the states after FDA approval.

Medicaid Utilization Information means the information on the total number of units of each dosage form and strength of the labeler's covered outpatient drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the state Medicaid agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991 or drugs dispensed prior to a labeler's active start date in the Medicaid Drug Rebate Program). The Medicaid utilization information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid for prescriptions during the quarter by NDC number. A state may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, best price.

National Drug Code is the identifying drug number supplied to the Food and Drug Administration by the labeler. For the purposes of the drug rebate agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code.

Net Sales means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

Nominal Price for purposes of excluding prices from the best price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

Non-innovator Multiple Source Drug shall have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act. It also includes covered outpatient drugs approved under an ANDA or AADA.

Quarter means calendar quarter unless otherwise specified.

Rebate Payment means, with respect to the labeler's covered outpatient drugs, the quarterly payment by the labeler to the state Medicaid agency, calculated in accordance with section 1927 of the Act and the provisions of the signed rebate agreement.

Rebate Per Unit (See Unit Rebate Amount)

Secretary means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement the drug rebate agreement has been delegated.

Single-Award Contract means a contract between the Federal Government and a labeler resulting in a single supplier for a covered outpatient drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single-award contract.

Single-Award Contract Price means a price established under a Single-Award Contract.

Single Source Drug will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act. It also includes a covered outpatient drug approved under a PLA, ELA or ABA.

States means the 50 states and the District of Columbia.

State Medicaid Agency means the agency designated by a state under section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

Unit means drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The labeler will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions.

Unit Rebate Amount means the computed unit amount to which the Medicaid utilization information is applied for the rebate payment due. This term is synonymous with the terms Rebate Per Unit and Rebate Amount Per Unit, as used by the states and labelers.

ACRONYMS

PROGRAM ACRONYMS

The acronyms listed below may not necessarily appear in this guide.
However, they are used within the Medicaid Drug Rebate Program and,
therefore, provided for your convenience.

AADA	- Abbreviated Antibiotic Drug Application
(the) ACT	- The Social Security Act
ADA	- Antibiotic Drug Application
AMP	- Average Manufacturer's Price
ANDA	- Abbreviated New Drug Application
BBA	- Balanced Budget Act
BL	- Baseline
BP	- Best Price
CMS	- Centers for Medicare & Medicaid Services (formerly HCFA)
CMSO	- Center for Medicaid and State Operations
CPI-U	- Consumer Price Index-Urban
DESI	- Drug Efficacy Study Implementation
DRP	- Dispute Resolution Project
DUR	- Drug Utilization Review
EAC	- Estimated Acquisition Cost
FDA	- Food and Drug Administration
FFP	- Federal Financial Participation
FUL	- Federal Upper Limits
HCFA	- Health Care Financing Administration (now CMS)
HMO	- Health Maintenance Organization
IND	- Investigational New Drug
IRS	- Identical, Related, and Similar
LTE	- Less Than Effective
MAC	- Maximum Allowable Cost
MCO	- Managed Care Organization
MDRI	- Medicaid Drug Rebate Initiative
NDA	- New Drug Application
NDC	- National Drug Code
NOOH	- Notice of Opportunity for Hearing
OBRA	- Omnibus Budget Reconciliation Act
OIG	- Office of the Inspector General
OMB	- Office of Management and Budget

OTC	- Over the Counter
OTG	- Operational Training Guide
PA	- Prior Authorization
PBM	- Pharmacy Benefit Manager
PHS	- Public Health Service
PLA	- Product License Application
PPA	- Prior Period Adjustment
PQAS	- Prior Quarter Adjustment Statement
ROSI	- Reconciliation of State Invoice
RPU	- Rebate Per Unit (Synonymous with URA)
TPL	- Third Party Liability
UPPS	- Units Per Package Size
URA	- Unit Rebate Amount (Synonymous with RPU)
VHCA	- Veterans Health Care Act

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R6

QUESTIONS

and

ANSWERS

FREQUENTLY ASKED QUESTIONS

In this section we have accumulated a list of questions we get from telephone calls, conferences, e-mails and letters. Our goal is to offer complete, concise and to-the-point answers in plain English. If you have a question, whether you are doing your first product/pricing submission or you are an "old timer" in the program, it may be best that you refer to this section with your question before calling or writing the drug rebate staff. This could save you time and give you a clearer understanding of your current problem. It is our attempt in this Q&A section to amass a large percentage of common problems that affect all users, both new and experienced.

We anticipate this section to be an ever-expanding list of questions and answers, so watch for future updates to the operations guide; your question may be included next!!

Q: Who do I contact regarding drug rebate questions?

A: Whether your questions are related to policy or operations, you can find a listing of drug rebate staff in section O of your OTG. This section provides a list of drug rebate functions and the staff members responsible for those areas. Also provided are listings of staff telephone numbers, fax numbers, addresses, and the website for the drug rebate homepage.

Q: What drugs can states restrict or deny coverage for? I understand that there are drugs that a state can restrict or exclude from coverage even though I have been led to believe that ALL my drugs will be covered by the states when I sign the CMS Medicaid Drug Rebate Agreement.

A: The following drugs, by their class or designation of medical uses, may be restricted or excluded from coverage by any state.

- Drugs, when used for anorexia, weight loss or weight gain
- Drugs, when used to promote fertility
- Drugs, when used for cosmetic purposes or hair growth
- Drugs, when used for symptomatic relief of cough or colds
- Drugs, when used to promote smoking cessation
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Nonprescription drugs
- Covered outpatient drugs, which the manufacturer seeks to require as a condition of sale, that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Barbiturates
- Benzodiazepines

Q: I am new to the Drug Rebate Program. What am I expected to send in,
       when, how, to whom and where?

A: After you, or a company representative, submits a signed copy of the rebate
       agreement, Baseline and initial pricing data is to be submitted on all
       outpatient drug products during the month following the quarter in which
       your agreement was postmarked. If your agreement was postmarked from
       January 1 through March 31, this data is due during the month of April. If
       your agreement was signed from April 1 through June 30, it is due during
       July, etc.

       You are expected to submit Baseline data on ALL products having NDCs
       that are FDA-listed as drugs and are covered as outpatient drugs. Baseline
       data is the basic information of the product which includes FDA Approval
       Date, Market Date, DESI code, etc. The data fields are included in the data
       dictionary, which is part of the agreement package sent to you originally.
       This data dictionary can also be found in the OTG sent to you after we
       received your signed agreement. Pricing data for the quarter you became
       effective is also due at this time. (See section F)

       Submission of your data is done based on the option selected when you or
       your company representative signed the rebate agreement and completed
       the contact and transmission option forms. The address for submitting data
       is contained in the agreement and in the OTG. We have provided a P.O.
       Box for regular mail and an address for overnight delivery. (See section O)

Q: My prices didn't change this quarter. Do I still have to send them in to
       you?

A: Quarterly pricing is due to us within 30 days after the end of each quarter.
       Whether your prices changed is not an issue. Your calculated AMP is
       based on specific sales only, with discounts, charge backs, returns, etc.,
       included to bring the gross dollars down to net dollars which is divided by
       total units sold. Because of the mix of sales, discounts, etc., even if your
       sales prices do not change, it is quite possible that your calculated AMP
       will change. Also, for those products where BP is included, BP is based on
       the lowest price you SOLD the product for during the quarter, NOT the

lowest price you offered it for sale. You may have several contracts where you sell a product for different prices. The company you sell to with the lowest price doesn't buy any product this quarter, but the second best does. That changes your BP for the quarter. (See section F)

Q: We have a new drug that has a Market Date as the last (working) day of the quarter and have no sales listed for that quarter, yet you require pricing information. What do I send you?

A: In this case, use the selling price as the AMP (BP also, if required) to satisfy the requirements of the system. There will be no rebate requests from states as there were no actual sales. (See section F)

Q: I had no sales in this quarter for an NDC. Should I report zeros for prices or not report any data this quarter for the drug?

A: Pricing is due to us every quarter on every active NDC ("active" means that the NDC has no termination date or the termination date is less than 4 quarters past the reporting quarter). Therefore, no sales does not mean no reporting or zero reporting. For any quarter, if you had no sales or if your AMP calculated to a minus figure due to adjustments, discounts, etc., go to the last quarter when a valid AMP was calculated and report that AMP for this quarter. (See section F)

Q: I sent pricing for a new product this quarter but it rejected because I didn't send baseline data. This is an "N" drug and doesn't require baseline data. What should I do?

A: Baseline (product identification) data is required for every product you sell under your labeler code that is classified as an outpatient drug. Sometimes there is some confusion between baseline data and baseline AMP. Baseline AMP is a field that is required for all "S" and "I" products having a Market Date less than 10-01-1993. Baseline data is the information we need to identify each product and includes such elements as Drug Type, Drug Category, DESI code, Unit Type, etc. (See section F)

Q: I have several package sizes of my product and sent pricing based on the sales of each one. You sent me an edit list stating that my pricing was incorrect and that you were using my highest AMP and lowest BP for ALL sizes. What gives?

A: When you have more than one package size of the same product (same strength and unit type), pricing is calculated slightly different from products having only one package size. Your AMP calculation is:

> Total units sold of ALL package sizes (adjusted for returns, chargebacks, etc.) ÷ into the total net sales dollars (adjusted for discounts, breakage rebate, etc.,) for ALL package sizes.

This gives you a "weighted" AMP for the product (9-digit NDC) that is to be reported for ALL package sizes (11-digit NDC) of the product. BP is not calculated or weighted. Instead, it is the lowest price per unit the product sold for during the quarter regardless of package size. The same (lowest) BP is reported for all package sizes of the same product. Remember this rule: Price by 9-digit, report by 11-digit. (See section F)

Q: I have a new package size of a product that just came on the market last quarter. I supplied Baseline data to you but some of it was rejected. For example, you wouldn't let me use the new market date for this package. Why not?

A: Even though you are required to report all product information by 11-digit NDC, pricing and MOST baseline information must be the same for all package sizes of a product (9-digit NDC), with the exception of Units Per Package Size (UPPS), Termination Date, and Product Name. The redesigned system will not allow reporting of different values in any of the other fields. (See section F)

Q: Since CMS changed the way it rounds the URA, and does so only for new or PPA records, I have a question regarding how this will work when reporting new package sizes of old products. Since the new package size must have all quarters of pricing completed back to the Market Date of the

oldest size, wouldn't that cause the new package size to have its old rebates calculated and, thus, have different values than the already existing package sizes?

A: No. The new package size will have the same URA values as the existing package sizes. When you submit information for a new package size, the system allows for specific information to be entered from your data, such as: NDC3, UPPS, and Product Name. All other information is taken from the old (already existing) package size. In a similar manner, all pricing *AND* URA information is copied from an old package size to the new package size and flags to calculate the URA for this new package size are turned off. That means that the integrity of the URA from the old package sizes is maintained by all new package sizes. PPAs are NOT generated for two reasons: 1) Nothing changed, thus PPAs are not warranted; and 2) There should never be any old utilization requests for this new size as it didn't exist before this quarter.

Q: I have an "I" (Innovator) product with a Market Date of 02-16-1997. When I established my Baseline data I included a Baseline AMP of .5126. I followed the URA calculation in the OTG to a "T" but still came up with a different URA than is reported to me by the states. Why?

A: Because your Market Date is beyond 09-30-1993, submitting your Baseline data with a value in the Baseline AMP does not do you (nor us) any good. If you read the quarterly pricing data definitions (section F), you will see that Baseline AMP is NOT reported for ANY drugs having a Market Date past (newer than) 09-30-1993. The calculated AMP from the quarter immediately AFTER market date is used IN PLACE OF Baseline AMP for CPI-U Creep calculations. Look at the AMP for Q2/1997. It may be different than your .5126 B/L-AMP. Also, make sure you are using the CPI-U value from March, 1997, NOT January, 1997, for your Baseline CPI-U. Recalculate using these figures and see if your calculation for URA matches ours. If not, contact one of the operations analysts listed in section O, of your OTG. (See section H)

Q: I got an invoice from a state and one of the NDCs has a zero URA. Do I ignore that one and just pay for the URAs that have an amount?

A: No. Your responsibility is to pay rebates on all valid NDCs reported to you by a state. If an NDC has zeros in the URA it is due to one of several reasons: 1) You did not report pricing to us on time for this quarter; 2) You reported pricing but it was rejected and you haven't had time to turn around a correction from the edit list; or 3) You reported pricing but when the URA was calculated it was more than 50% higher or more than 50% lower than the last quarter. In case #3, you should have received a 50/50 report showing NDCs that fall into this category. If the pricing you submitted was, in fact, correct, use the URA shown as the very last data element on the 50/50 report for computing the rebate to the state. If the prices you reported are wrong, calculate the URA using correct pricing, use the correct URA for paying the state, and send a correction record to us with your next quarter's pricing submission. (See sections F and G)

Q: I got my quarterly tape and some of the NDCs contain zeros in the URA field. Should I still include these on my invoices?

A: Yes. ANY utilization for ANY NDCs that match the quarterly file from CMS should be submitted to the proper labeler for rebate. If there are zeros in the URA field it is because the labeler either:

   • Did not supply pricing for the NDC this quarter;
   • Supplied pricing data but it was rejected (by us) and the labeler did not have enough time to resubmit the corrected data before we shut the system down for quarterly processing; or,
   • Supplied pricing data but when the URA was calculated it fell outside the parameters of the 50/50 edit.

(See section F)

Q: I have a product that came on the market in May, 2000. It is an "I" drug, thus, it requires a Baseline AMP and (every quarter) Best Price. When I submitted the product record, I included the Baseline AMP. Now, I have calculated the URA for all quarters since the product came on the market and the first 2 quarters match; however, since the 4th quarter, 2000, my URA is different from yours. I have followed the URA calculation in the Operations Guide, but cannot get my URAs to match those computed by CMS. HELP !!!

A: There are two quick observations. 1) ALL "S" and "I" products having a Market Date of 10-01-1993 or GREATER are NOT required to have Baseline AMP reported for them, and 2) your question suggests that your product's price is going up pretty quickly if the "creep" calculation is already involved.

Check to make sure you are calculating your AMP correctly. With that being said, the Baseline AMP you filled in with your initial product record to us has been stored in the Baseline AMP field but is ignored by the system. Check your calculated AMP for the July, 2000 quarter to see if it is different from the Baseline AMP you are using in your URA calculation. If it is, perform the calculation again using the July quarterly AMP in place

of the Baseline AMP and see if your URA and ours are now in agreement. If the two figures STILL don't agree, make sure you are using the CPI-U value from June, 2000. If that still doesn't work, try a new calculator. By the way, the reason your URA calculation for the first 2 quarters this product was on the market matched ours was because for the first two quarters (Market Date quarter plus the next quarter) only the first part of the URA calculation is performed (AMP * 15.1% or AMP − BP, whichever is greater). There was no CPI-U creep involved.

Many people still get confused over the changes OBRA'93 made to the values used in the CPI-U creep portion of the URA calculation. Beginning with the 4th quarter 1993 and forward, when the CPI-U CREEP calculation is performed for **ALL "S" and "I"** products having a **Market Date equal to 10-01-1990 or GREATER,** the **CPI-U creep** portion of the URA calculation uses the calculated **AMP** from the **quarter AFTER Market Date _IN PLACE OF_** the **Baseline AMP** and the **CPI-U value** from the **month PRIOR to the calculated AMP** quarter _IN PLACE OF_ the **Baseline CPI-U.** That does not mean that **YOU** physically include this value in the Baseline AMP field. It simply means that you **USE** this value **IN PLACE OF THE _BASELINE AMP_** when doing the **CPI-U creep** portion of the URA calculation. (See section H)

Q: If my company sells a product to another company are we responsible for reporting prices and/or paying rebates? If so, for how long?

A: There are actually two answers depending on the sale and how the product will be sold by the new company.

First and foremost, any products sold under your company's NDC are the responsibility of your company for reporting prices and product changes and, ultimately, paying rebates. If an agreement is worked out between the two companies where the new company will supply pricing/product information, so be it. However, if the pricing comes to CMS late or does not come in, CMS will hold the owner of the labeler code responsible. Likewise, all invoices, edit reports, etc., will be sent to the holder of the labeler code. If the new company continues to sell the product under the old NDC, this practice continues.

If the new company starts packaging and selling the product under its labeler code, all responsibility for reporting and paying under the new NDC, now completely falls with the new company. At this point, one last thing must be done with products under the old NDC. The Termination Date (last date the product can be dispensed from the shelf) field must be updated on the CMS MDRI Master file, via your quarterly reporting. Also remember, when a product terminates, pricing is due to CMS for 4 quarters beyond the termination date. You continue to calculate prices quarter after quarter until the last quarter the product is sold. From that point on, use the calculated prices from the last quarter sold until and including the 4th quarter after the termination date. Once that 4th quarter has past, stop reporting prices. (See section F)

Q: I have a product that is going to be discontinued. What do I send you as termination date; the date we stopped making it or the date we stopped selling it?

A: Neither. Termination Date equals one of two dates:

1. Date product was removed from pharmacy shelves; or
2. Date of shelf life (last day it can be dispensed) of last lot sold.

It doesn't matter when a company stops making or selling a product. The Termination Date is equal to the last day the product may be dispensed. (See section F)

Q: I sent termination dates on several of my products last quarter but CMS is still asking for pricing data for these NDCs. Why, and what price do I send since there are no longer sales of these products?

A: Pricing data for terminated products must continue to be sent to CMS for 4 quarters **beyond** the termination date. This is necessary because Medicaid law states that pharmacies have up to one year to submit reimbursement claims to the state. The pricing data you should submit for the 4 quarters beyond the termination date is the calculated pricing from the last quarter of sales. (See section F)

Q: I prefer to use my FirstData Bank (FDB) file for information on each labeler. Is there a down side to doing this?

A: Several. Your FDB file serves a valuable purpose in your everyday Medicaid processing. This file, however, does NOT necessarily contain all of the correct data for running your Drug Rebate System. The CMS quarterly file contains information on ALL active NDCs reported to us by the labelers. It also contains the official CMS values for each field.

If, for example, the labeler submits baseline data for a new product and the DESI code INCORRECTLY contains a value of "2," where it should have a value of "5," and it gets onto the CMS file, the state is covered for ALL prescriptions it pays for until CMS corrects the mistake. If, however, the CMS file contains the CORRECT value of "5" and the FDB file contains the INCORECT value of "2" and the state uses the FDB value, the state is NOT covered for FFP and CMS will NOT suggest to the labeler that they make a rebate payment to the state for all prescriptions the state paid for while using the incorrect value. There are several DESI values on the FDB file. There are also several Termination Dates, including an obsolete date, which CMS doesn't even recognize. Remember, when in doubt about whose data are correct, CMS's data always takes precedence.
(See section G)

Q: Do I have to wait for the CMS tape before sending my invoices out? I usually have my utilization calculations done and my invoices ready long before the 45 days after the end of the quarter when the CMS tape gets here.

A: No, you do not have to wait for the quarterly CMS tape to send out your invoices. HOWEVER, this means that ALL of your invoices must go out with zeros in the URA field and thus, the amount owed the state field, as well. This also means that you are having the labeler calculate every URA for every NDC on their file. This could delay their rebate check to you. Also, do you EVER use the CMS tape? If you do not use it for supplying URA values, do you match it to your file to make sure your NDCs are active and accurate? (See section G)

Q: I sent my invoice to labeler "X", but they didn't pay for the NDCs that they said weren't on the CMS tape. What can I do?

A: First, you should always use the CMS tape. The quarterly tape (or cartridge) CMS sends contains one record for every ACTIVE NDC on our file. If you have paid for an NDC that is NOT on our file you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid NDC, you may have to go back to the pharmacy to recoup your funds. (See section G)

Q: Am I under obligation to pay a state invoice even if it is 2 or 3 months late? I am told that I have 37 days after postmark of a state invoice to pay or be subject to interest payments, yet, states constantly send their invoices long after the "60 days past the end of the quarter" timeframe they are supposed to meet.

A: Section 1927(b)(2) of the Act does, in fact, require a state to submit invoice data to labelers within 60 days after the end of a quarter. There is no provision in the law to relieve labelers from the requirement to pay rebates regardless of when the invoice is received. Of course, the labeler's 37-day clock never begins until the postmark of the invoice, thus relieving the labeler of paying prior to 90 days past the end of the quarter.
(See section F)

Q: I am new to the program and have submitted pricing to you as required under section 1927 of the Act and have started getting my first state invoices. The URA field on the invoices is showing that I owe about 100 times more in rebate than I sold the product for. Why are these invoices coming to me with these extremely high rebate amounts due?

A: Check the pricing data you sent to us. Are you submitting prices based on **ONE** of your Unit Type or on the whole package? Please remember that when you submit your Baseline data for a product you include a Unit Type that is equal to the lowest dispensable unit of the product (TAB, ML, etc.). **ALL AMP and BP** pricing is to reflect **ONE UNIT** of the **UNIT TYPE**. If your pricing looks correct, contact one of the drug rebate staff for assistance. (See section F)

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